EFFECTIVENESS OF ICE CUBE APPLICATION UPON PAIN PERCEPTION OF CHILDREN DURING INTRA MUSCULAR INJECTION

BY

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A DISSERTATION SUBMITTED TO THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF

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DECLARATION

I hereby declare that the present dissertation entitled **"Effectiveness of Ice Cube Application Upon Pain Perception of Children During Intra Muscular Injection"** is the outcome of the original research work undertaken and carried out by me under the guidance of **Dr. Latha Venkatesan,** M.Sc (N)., M.Phil (N)., Ph.D (N)., Principal and professor in Obstetric and Gynaecological Nursing Department, Apollo College of Nursing, **Mrs. Jamuna Rani. R,** M.Sc (N)., MHRM, Reader, Apollo College of Nursing, Chennai. I also declare that the material on this has not found in any way, the basis for the award of any degree or diploma in this university or any other universities.

M.Sc Nursing II Year

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SYNOPSIS

An Experimental Study to Assess the Effectiveness of Ice Cube Application Upon Pain Perception of Children during Intra Muscular Injection at Selected Hospital, Chennai.

The Objectives of the study were,

1. To assess the level of pain perceived during intra muscular injection by control and experimental group of children.
2. To determine the effectiveness of ice cube application by comparing the pain perception of control and experimental group of children during intra muscular injection.
3. To determine the level of satisfaction of mothers regarding ice cube application during intra muscular injection in the experimental group of children.
4. To find out the association between selected demographic variables and pain perception during intra muscular injection in the control and experimental group of children.
5. To find out the association between selected clinical variables and pain perception during intra muscular injection in the control and experimental group of children.

The conceptual frame work for the study was developed on the basis of Roy's adaptation model, which was modified for the present study.

An experimental research approach with post test only design was used to achieve the objectives of the study. The present study was conducted in Durgabai

Deshmukh General Hospital and Research Centre, Andhra Mahila Sabha Chennai, with the sample size of 60 children including 30 in control group and 30 in experimental group who satisfied the inclusion criteria using systematic random sampling technique.

An extensive review of literature and expert guidance laid the foundation to development of tools such as demographic variable proforma, clinical variable proforma, FLACC scale and mother's satisfaction rating scale to assess the level of satisfaction. The data collection tools were validated and reliability was established. After two weeks of pilot study, the data collection for the main study was conducted for six weeks.

The investigator administered demographic and clinical proforma to the parents in control and experimental group. The children in the control group were assessed using FLACC scale for pain perception after intramuscular injection without any intervention. In experimental group, ice cube application was given for a period of 30 seconds before intramuscular injection. At the end of this period, intra muscular injection was given and post assessment of pain was done immediately for 1 minute by using observation check list and FLACC scale. The level of satisfaction of mothers regarding ice cube application was assessed using satisfaction rating scale.

Major findings of the study were

- Majority of the children belonged to Hindu religion (70%, 73.3%) and living in urban area (43.3%, 83.3%), significant percentage of the children were males (66.6%, 36.6%), most of the children were in the age group of >17 months (36.6%, 66.6%), with the family income between Rs.10001- 15000 (43.3%, 36.6%) in control and experimental group of children respectively.

- Most of the children (56.6%, 46.6%) were less than 80 centimeters tall, (56.6%, 50%) of children weighed < 11 kilograms, (43.3%,53.3%) received pentavac injection and none of the children had history of allergic reaction in control and experimental group of children respectively.
- The mean and standard deviation of pain perception of children in the control group was Mean=7.4, SD=1.3 and in experimental group Mean=3.3, SD=1.51 respectively. The 't' value of 11.7 was highly significant at P< 0.001 level of significance. Hence, the null hypothesis H_{01} was rejected.
- There was no significant association between selected demographic variables and pain perception at $p<0.05$ in control group of children.
- There was a significant association between the gender of the child (χ^2 =5.68, df=1), type of family (χ^2 =4.35, df=1) and pain perception at $p<0.05$ in the experimental group and no significant association between other demographic variables and pain perception in the experimental group of children. Hence the null hypothesis H_{02} was partially rejected with regard to the gender of the child and type of family in experimental group of children and partially retained with regard to other demographic variables in control and experimental group of children.
- There was no significant association between selected clinical variables and pain perception in control group of children.
- There was a significant association between the height of the child (χ^2 =4.85, df=1), weight of the child (χ^2 =7.03, df=1) and pain perception at $p<0.05$ in the experimental group of children and no significant association between other clinical variables and pain perception in experimental group of children. Hence,

the null hypothesis H_{03} was partially rejected with height and weight of the children in experimental group and partially retained with regard to other clinical variables in control and experimental group of children.

- The study findings revealed that majority (77%) of the mothers were highly satisfied and significant (23%) of the mothers were moderately satisfied regarding the ice cube application during intramuscular injection. The intervention also enhanced the perception and confidence among the mothers to support the child, in reducing the pain experienced during intramuscular injection.

Recommendations

- The study can be conducted on larger sample to generalize the results.
- The study can be conducted in different settings
- The study can be conducted for pain management during other invasive procedures.
- A comparative study can be conducted to evaluate the effectiveness of various other interventions to reduce pain.
- The study can be conducted among children of different age groups.
- A comparative study can be conducted to assess the effectiveness of ice cube application with other intervention like Emla cream application during intramuscular injection.

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CHAPTER I

INTRODUCTION

Background of the Study

"We've learned a lot about how to safely treat pain, but there's a substantial gap between what we know about pain in children and what we do."

-Howard

The word 'child' comes from the Germanic word cild - "child". Also in Old English meaning "a youth of gentle birth". Children are amazingly efficient and very enthusiastic towards the environment. In the beginning of child hood, the child begins to interact with others outside the family. During this period, the parents should be lovely, caring, stimulating and identifying the needs and confirm the expectation of the society in them. India's total child population, between the age group of 0 - 14 years is 32.3%. Most children undergo painful procedures.

The International Association for the Study of Pain (IASP, 1979), defined pain as "an unpleasant sensory and emotional experience associated with actual or potential damage, or described in terms of such damage". It is the most common reason for seeking health care. The health personnel must have the knowledge and skills to assess pain, to implement pain relief strategies, and to evaluate the effectiveness of these strategies, regardless of the setting.

The physical change and development of children is dramatic when compared with other ages. The more frequent caregiver for a child is the mother. They undergo many stresses while taking care of their children. When the child is ill or undergoes any painful procedures, will have anxiety, stress and fears. It is the responsibility of the

nurse to give emotional support, guidance and full explanation of the procedure to the parents. The nurse can educate the parents about the procedures and ways of providing care for their children.

Illness and hospitalization expose children to unfamiliar and unpleasant feelings. Since children have little experience and comprehension of pain, it can cause intimidation and anxiety for them. Millions of children undergo procedures, which cause considerable distress. Children requiring needle stick such as injections, IV catheters and blood sampling, view these procedures as frightening and as a significant source of pain.

Pain in children, and whether children feel pain, has been the subject of debate within the medical profession for centuries. Prior to the late nineteenth century, it was generally considered that children get hurt more easily than adults. It was only in the last quarter of the 20th century, that scientific techniques were finally established children definitely do experience pain, probably more than adults and has developed reliable means of assessing and treating it.

Injections for vaccinations, the most common source of iatrogenic pain in childhood, are administered repeatedly to almost all children throughout infancy, childhood and adolescence. The pain associated with such injections, is a source of distress for children, their parents and for those administering the injections. If not addressed, this pain can lead to pre procedural anxiety in the future, needle fears and health care avoidance behaviours, including non adherence with vaccination schedules. It is estimated that up to 25% of adults have a fear of needles, with most fears

developing in childhood. About 10% of the population avoids vaccination and other needle procedures because of needle fears.

Pain is a global health problem which exists from the birth to the last stage of the life. It's a very unpleasant sensation that cannot be shared with others. Pain is defined as "an unpleasant sensory and emotional experience arising from actual or potential tissue damage or described in terms of such damage".

The American Academy of Pediatrics and American pain society, addressed the need for appropriate pain management in children in their joint statement presented in 2001. They noted that, despite comprehensive research, anecdotal experience and ample knowledge of the past 10-15 year, the assessment and treatment of pain in children frequently remain inadequate.

Need for the study

Injections are the most frequently used procedures, with an estimated 12 billion, administered throughout the world, on an annual basis of these 5% or less are for immunization, according to WHO and rest are given for curative purposes. The prevalence of injections in European countries was 5.6 - 11.3 injections per persons per year. The lowest annual number of injections was in America, about 1.7-1.9 injections per persons per year. The prevalence of injections in South East Asia, the annual ranges from 1.7 - 11.3 injections per persons per year.

In India 77.2% of rural and 80 % of urban children are immunized with vaccines annually. The children vaccinated will experience severe to moderate pain. There are many non-pharmacological measures to reduce pain, one of which is ice application at the injection site prior to injection.

Immunization is the most aversive of medical procedures for healthy infants and children. Studies based on 2005 census revealed that immunization program could cover about 100% of target children in India. Only about 63% of children received all the vaccines (BCG, DPT, OPV, and Measles), during immunization. Painful procedures are likely to be confounded with anticipatory and concurrent anxiety, usually considered together as possible related distress.

An experimental study was done on effectiveness of ice application, at selected point (LI- 4) prior to intra muscular injection in reducing pain among 60 children between 15-18 months, attending the immunization clinic. Ice application was given to children under experimental group for 30 seconds prior to intramuscular injection. At the end of this period, intramuscular injection was given and assessment of pain was done immediately for one minute by using observational checklist and Wong and Backer faces pain scale. The study finding revealed that majority (80%) of the children in experimental group, had mild pain level after ice application. The study findings revealed that there was a highly statistically significant difference, in level of pain among children between experimental and control group at $p<0.001$ level of significance.

A combination of pharmacological and non-pharmacological interventions can ensure the highest standard of care in the management of pain in children. In infants, ice application slows the nerve impulse in the area, which interrupts the pain spasm reaction between the nerves. The cold makes the vein into the tissue to contract, reducing pain. Once the cold goes off, the vein overcomes compensate and dilate blood rushes into the area, which in turn has an analgesic effect.

There is no systemic pharmacological treatment are appropriate to provide pain relief during minor procedures, such as immunization, injections in this age group. An intervention that is cost effective and has no ill effect would be ideal for use in primary care setting for child receiving injection. Research has shown that the ice cube application is effective treatment to decrease pain perception in children during injection.

Minimizing pain during childhood vaccination can help to prevent distress, development of needle fears and subsequent health care avoidance behaviours, such as non-adherence with vaccination schedules. More positive experiences during vaccine injections also maintain and promote trust in health care providers. So nurses can use simple interventions to relieve procedural pain in children and promote comfort for them.

A comparative study was conducted by Hasanpour, et al. (2003) to determine the effects of two non- pharmacological pain management methods for intramuscular injection pain in children. 90 samples were chosen randomly and were divided into 3groups, the first group received distraction and the second group received cold therapy and the third group received routine care. Oucher scale was used to measure

the pain intensity .Average pain intensity in local cold therapy, distraction and the control group was 26.3, 34.3 and 83.3 respectively. The finding of the study shows that cold therapy has a significant effect on pain reduction

Assessing and managing a child with pain is a daily problem for nurses. Nurses implement the orders and work closely with patients to facilitate the healing process. Researcher found that no pain interventions were given to children during injection in hospitals. This stimulated the researcher to identify the simple, safe and easy method of pain intervention during injection thus motivated to conduct an experimental study to assess the effectiveness of ice cube application upon pain perception of children during intra muscular injection and to obtain the level of satisfaction of the parents towards the intervention.

Statement of the Problem

An Experimental Study to Assess the Effectiveness of Ice Cube Application Upon Pain Perception of Children during Intra Muscular Injection at Selected Hospital, Chennai.

Objectives of the Study

1. To assess the level of pain perceived during intra muscular injection by control and experimental group of children.
2. To determine the effectiveness of ice cube application by comparing the pain perception of control and experimental group of children during intra muscular injection.

3. To determine the level of satisfaction of mothers regarding ice cube application during intra muscular injection in the experimental group of children.
4. To find out the association between selected demographic variables and pain perception during intra muscular injection in the control and experimental group of children.
5. To find out the association between selected clinical variables and pain perception during intra muscular injection in the control and experimental group of children.

Operational Definitions

Effectiveness

In this study, it refers to the expected and desired change in the level of pain perception of children after application of ice cubes in LI-4 (acupressure) point and is measured by FLACC scale.

Ice cube application

In this study, it refers to the application of ice cubes to the selected site ie, the web between the thumb and index finger of hand LI-4 (acupressure point) for a period of 30 seconds prior to intra muscular injection in children.

Pain perception

In this study, it refers to the pain experienced by children during intra muscular injection as measured by FLACC scale.

Children

In this study, it refers to the children age between 15-18 months receiving intra muscular injection at selected hospitals in Chennai.

Intra muscular injection

In this study, it refers to the administration of 0.5 ml of an immunizing agent through intramuscular route in vastus lateralis muscle of anterior thigh of children.

Assumptions

- Children perceive pain during administration of injection.
- Invasive procedures evoke a pain response in children.
- Ice application is one of the strategies used for pain reduction.
- Distractions can modify children's response to pain.
- Every child is unique and responds in a unique way, to pain.
- Application of ice stimulates the large diameter sensory fibers, that synapse in the dorsal horn of the spinal cord, which produces an inhibitory effect on the transmission of incoming pain signal.

Null Hypothesis

H_{01}: There will be no significant difference in pain perception during intra muscular injection among control and experimental group of children.

H_{02}: There will be no significant association between selected demographic variables and pain perception during intra muscular injection in the control and experimental group of children.

H_{03}: There will be no significant association between selected clinical variables and pain perception during intra muscular injection in the control and experimental group of children

Delimitations

The study was delimited to children who are:

- Between the age group of 15 – 18 months.
- Receiving either DPT vaccine or DTP booster – 1, Hib booster, MMR -1, Pentavac.
- Mothers willing to participate in the study and know either Tamil or English.

Conceptual Framework

The conceptual framework deals with the interrelated concepts that are assembled together in some rational schemes by virtue of their relevance to a common theme (Polit and Beck , 2008).

Conceptual framework of the present study is based on modified Sr. Callista Roy's adaptation Model (1970). According to Sr. Callista Roy, a person in an adaptive system and the need for adaptation is triggered by various stimuli. The human beings are biopsychological being in the adaptive system, who copes within the environmental change through the process of adaptation. Within the human system there are four subsystem, response modes such as physiological needs, self concept, role function and independence. These sub systems constitute an adaptive mode that provides a mechanism for coping with environmental stimuli and change. The goal of nursing according to this model is to promote adaption of the individual for various stimuli from the environment during health and illness.

The main concept of this model are input, throughput, output and feedback.

Input

In this study input refers to the demographic variable such as age, sex, religion, place, height weight.

Throughput

In this study throughput refers to providing nursing intervention that is ice cube application at LI – 4 point prior to intra muscular injection. The person uses ill as adaptive system. Experimental group is exposed to the intervention before administration of intramuscular injection and assess the level of pain by FLACC pain scale. Control group is allowed hospital routine and assess the level of pain is assessed by using FLACC pain scale.

Out put

It refers to the child's patterns behaviour. These patterns may be observed by FLACC scale. These responses provide feedback for the system. Roy's state that out put of the system is either adaptive response or non adaptive responses. Non adaptive response includes severe pain > 75%. Cry, body restraints, grabs, vigorously and restrained. Adaptive response includes mild pain < 50%, child does not cry, body is at rest, legs are relaxed and no grabbing.

Feedback

For adaptive response enhancement will be given and the nonadaptive response area reinforces will be given.

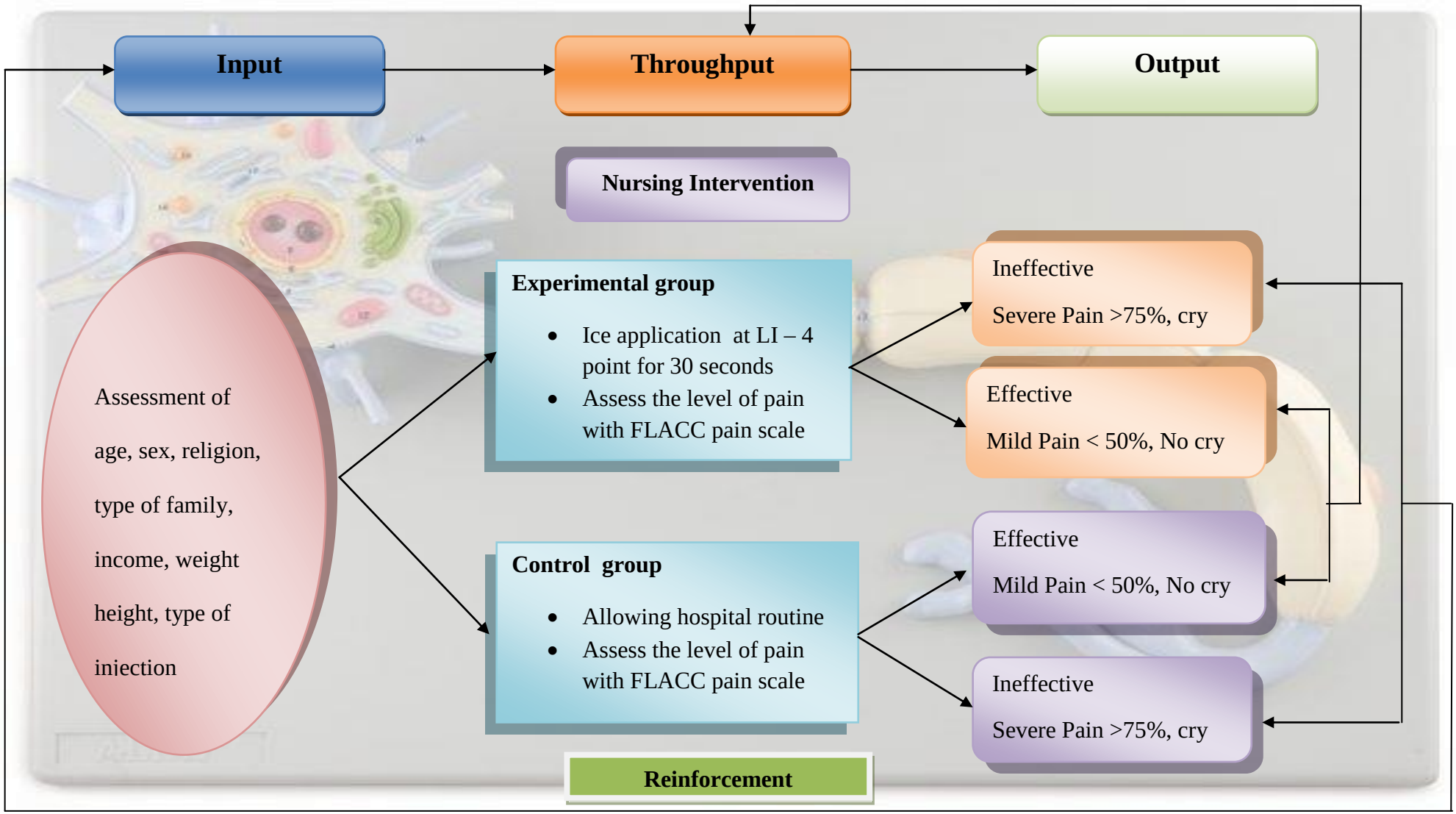

Fig:1 Conceptual Frame Work Based On Modified Roy's Adaption Model (1970)

Projected Outcome

Ice cube application during intramuscular injection, will help the children to have decreased pain perception and mother's satisfaction. The intervention will be affordable, safe and easy to administer.

Summary

This chapter has dealt with the background, need for the study, and statement of the problem, objectives, operational definitions, assumptions, null hypotheses, delimitations and conceptual framework.

Organization of the Report

Further aspects of the study are presented in the following five chapters.

In chapter II : Review of literature

In chapter III : Research Methodology which includes research approach, design, Setting, population, sample and sampling techniques, tool description, content validity and reliability of the tool, pilot study, data collection procedure and plan for data analysis.

In chapter IV : Analysis and interpretation of data.

In chapter V : Discussion

In chapter VI : Summary conclusion, implication and recommendation.

The report ends with selected references and annexure.

CHAPTER II

REVIEW OF LITERATURE

Review of literature helps the research to build on existing work he or she should understand what is already known as topic (Polit & Beck, 2008).

Review of literature helps to plan and conduct the study in a systemic manner. Review of literature is the task of reviewing literature which involves the identification, selection, critical analysis and reporting of existing information on the topic of interest. It provides the basis to locate the data, new ideas that need to include in the present study. It helps the researcher to find the accurate data that could be used for supporting the present finding and drawing conclusions.

This chapter deals with a review of published and unpublished research studies and related material for the present study. The review helped the researcher to develop an insight into the problem and build the foundation of the study.

The review of literature in this chapter has been presented under the following headings.

- **Studies related to pain in children**
- **Studies related to alternative therapies for reducing pain**
- **Studies related to acupressure as a pain relief measure**
- **Studies related to ice application at LI – 4 (acupressure) point to reduce pain.**

Literature Related to Pain in Children

Joseph (2009) in his literature on evidence based option to improve routine immunization stated that topical anesthetics in particular pre-injection EMLA cream, reduce injection related pain. However it is expensive and requires time to act. Non pharmacological intervention includes sweetened solution such as sucrose water although it does not work beyond one year of age. A combination of direct parental contact and sucrose seems to have an additive beneficial effect.

A descriptive study conducted by Vak (2007) on children to view the sources of pain and explore the views on pain relief strategies. An exploratory cross sectional descriptive design and writes technique was used to investigate on what aids the children to think at the time of experiencing pain. The sample was composed of 33% boys and 64% girls of 4 – 16 years. The result has shown that mean ± S.D: 9.25, ± 3.04 and few were different from the mean presented in the children texts and drawing based on developmental stage and on difference based on gender.

Owens (2004) in an article on comprehensive review pain measured for children aged between 0 and 3 years discussed their applicability to the group of children. Search of electronic data based and other electronic sources were supplemented by hand review of relevant journals to identify published measures for use in children aged between 0 and 3 years. Twenty eight pain measures were identified in the literature nine for neonates, ten for infants and nine for children aged between one and 3 years.

A descriptive study investigate the prevalence of pain and characteristic of pain (frequency, duration, intensity) among children and compared across different age and

gender conducted by Priyadarshini Johnson et al. in 2004. In this study about 735 children from school were surveyed, in which results showed that 715 (97.3%) have answered the questionnaires related to pain completely. The study concluded that the prevalence of pain, is increased with age and more pain was complained by female children.

Literature Related to Alternative Therapies for Reducing Pain

A randomized placebo, controlled trial was conducted to assess the efficiency of oral sucrose as an analgesic given during routine immunization among 100 children by Barnhill in 2008. The study has recommended that oral sucrose is an effective and easy to administer short acting analgesic during routine immunization.

In 2008, an experimental study to identify that a multidisciplinary approach is necessary to reduce the pain level in children, by using randomized trial on 90 children undergoing painful procedures was conducted by Chung. The study results recommended that medical and paramedical professionals can use pain management techniques like deep breathing imagery, acupressure and distraction tools. These methods are effective with no side effects.

Keritzer (2008) critically appraised all systematic reviews on the effectiveness of acute procedure related to pain management in hospitalized children. The published systematic reviews and meta analysis of pharmacological and non - pharmacological managements of acute procedure related pain in hospitalized children aged one to seven years were evaluated. Results showed that critical appraisal of pharmacological pain intervention indicated that amethocaine (local surface anaesthetic) was superior to

EMLA for reducing needle pain and distraction hypothesis was non pharmacological intervention, effective for management of acute procedure related pain in hospitalized children.

A comparative study to investigate the efficacy of combined transcutaneous acupoint electrical stimuli (TAES) and electromagnetic millimeter wave (EMMW) therapy. It is an add on treatment for pain relief and physical functional activity enhancement among children was conducted by Lee in 2007. In this study he used non blinded design among 47 children with ten sessions of treatment. Results showed the base line Visual Analogue Scale Score for the intervention and control group were 5.43 and 5.18 respectively at (p value < 0.05) level of significance. The study results that there is a reduction in pain intensity and stress immediately after the eight sessions of treatment.

An article on alternative therapies for pain by Zonna in 2003 written and shared that non pharmacological therapies are very effective to reduce procedural illness or injury related pain. It includes application of heat or cold or massage to the affected body areas, distraction techniques like toys, games, use of deep breathing and relaxation technique.

Battle (2002) presented an article on knowing about massage and stated that an hour or two hours spend on the application process of massage with regular interval is possible to superinduce a feeling of and a desire for response which often stimulate sound sleep and reduction of pain.

Literature Related to Acupressure as a Pain Relief Measure

Smith (2005) in his article on complementary therapies, stated that increasingly individuals are turning to complementary therapies, to reduce or cope with chronic pain. Acupressure was one of the oldest complementary therapies, originated from china more than 2500 years ago. It has steadily gained popularity in the United States, over the last few decades, as a modality for pain relief among both practitioners and patients. In 1997 the National Institutes of Health Consensus Conference concluded that acupressure point stimulates release of endorphins and other neurotransmitters in the brain and should be considered as an appropriate pain treatment option.

A comparative study by Hsieh (2004) conducted with the aim, to compare the efficacy of acupressure, with that of physical therapy in reducing pain. A total of 146 children with pain were randomly assigned to two groups, where 69 children in the acupressure group and 77children in the physical therapy group. The mean post treatment pain score after a four week of treatment (2.28; SD = 2.62) in the acupressure group was significantly lower than that in the physical therapy group (5.05; SD = 5.11). The result suggested that acupressure is an effective alternative medicine in reducing pain.

An experimental study to find the effectiveness of massage at the acupressure point for reducing pain in children after injection was conducted by Klein (2004). The study among 120 children between age of one to five years of age, with post test only design. The result shows that massage at acupressure point is very effective in reduction of pain after injection.

Yip (2004) conducted an experimental study to access the effect of acupressure using an aromatic essential oil as a treatment of pain relief among children age between 0-15 years. A course of 8-session manual acupressure with lavender oil over a 3 week period. The baseline VAS score for the intervention and control groups were 5.12 and 4.91 out of 10, respectively (*P*=0. 72). One month after the end of treatment, compared to the control group, the manual acupressure group had a 23% reduced pain intensity (*P*=0. 02), 23% reduced neck stiffness (*P*=0. 001), 39% reduced stress level (*P*=0. 0001), improved neck flexion (*P*=0. 02), neck lateral flexion (*P*=0. 02), and neck extension (*P*=0. 01). However, improvements in the functional disability level were found in both the manual acupressure group (*P*=0. 001) and control groups (*P*=0. 02). The result shows that it was an effective method of pain relief in children and no adverse effect were reported.

An experimental study to examine the efficiency of auricular acupressure in decreasing pain intensity in children with invasive procedure was conducted by Alimi in 2003. 90 children were randomly divided in four groups. One group received two course of auricular acupuncture at point with an electro dermal signal being detected and two placebo groups received auriculo acupuncture at point with no electro dermal signal and one with auriculo seeds fixed at placebo points. The result had shown that greater reduction of pain intensity from auricular acupuncture for the children.

Literature Related to Ice Application at LI – 4 point to Reduce Pain

Bellamkonda (2008) in his study to assess the effectiveness of ice application at LI – 4 point prior to injection in reducing the pain. It was conducted on 60 children

between the age of fifteen to eighteen months. The study result shows that 80% of the children in the experimental group had mild pain perception after ice application at LI-4 point.

An experimental study to assess the effectiveness of ice application at LI – 4 point for reducing the pain was conducted by Lischer in the year 2007. It was conducted on 250 children between the age of one to five years. The study result has shown that, this method was very effective in reduction of pain with no side effect. The study recommended that any health personnel can use this method safely and effectively because no side effect can be identified.

In 2006 a descriptive study was conducted by Long, to assess the opinions of acupressure regarding ice application at LI- 4 point for reduction of pain by other health professionals. The study results were concluded that 80% of acupresurists shared that any medical knowledgeable people can use it. 20% of them are told some training is needed for other people who are applying ice in order to apply acupressure effectively at specific points.

An experimental study to assess the effectiveness of ice application at LI – 4 point for the reduction of dental pain in 120 schoolchildren was conducted by Charles in the year 2006. The sample was selected by using simple random method and the pain level was assessed. The study result has shown that 74% of children were having mild pain, 14 % of children had moderate pain and 12% of children with no pain. The result shows that application of ice at acupressure point ie, LI-4 is very effective in reduction of pain after injection.

Summary

This chapter has dealt with review of literature related to the problem stated. The literatures presented here were extracted from Medscape, Journal of Indian Pediatrics and Journal of complementary and alternative medicine. It helped the researcher to understand the impact of the problem under study. It has also enabled the investigator to design the study, develop the tool and plan the data collection procedure and to analyze the data.

CHAPTER III

RESEARCH METHODOLOGY

The methodology of the research study is defined as the way the data is gathered in order to answer the question to analyze the research problem. It enables the researcher to project the blue print of the research undertaken. The research methodology involves a systemic procedure by which the researcher starts from the initial identification of the problem to its final conclusion (Polit & Beck, 2008). The present study was conducted to assess the effectiveness of ice cube application upon pain perception of children during intra muscular injection.

This chapter deals with a brief discussion of different steps undertaken by the researcher for the study. It involves research approach, research design, setting, population, sample and sampling technique, selection of tool, content validity, reliability, pilot study, data collection procedure and plan for data analysis.

Research Approach

Research approach is the most significant part of any research. The appropriate choice of the researcher approach depends on the purpose of researcher study which is undertaken. Experimental research is an extremely applied from of research and involves finding out how well a program, practice or policy are working (Polit & Beck, 2008).

In this study, the researcher wanted to assess the effectiveness of ice cube application upon pain perception of children during intra muscular injection. After

extensive review of the literature the researcher found that the experimental approach was the best suit approach.

Research Design

Polit and Beck (2008) defined research design as the overall plan for addressing a research question, including specifications for enhancing the study's integrity. A true experimental research design was used for this study. True experimental research is a powerful method available for testing the hypothesis of cause and effect relationship between variables. It has the characteristic feature such as manipulation, control and randomization. Randomization was carried out to select 60 samples and to assign them in the control and experimental group. Ice Cube application was given as intervention in the experimental group.

In this study, post test only design was adopted. The researcher manipulated the independent variable i.e., ice application to the experimental group of children. The effectiveness of ice cube application upon the independent variable i.e., the pain perception in children was computed. The research design is represented diagrammatically as follows:

Post test only design

R - 0

R X 0

R - Randomization

X - Intervention

O - Post test in control and experimental group

Variables

Independent variable

The variable that is believed to cause or influence the dependent variable is the independent variable (Polit & Beck, 2008). In this study, the independent variable is ice cube application.

Dependent variable

The variable hypothesized to depend on or be caused by another variable is the dependent variable (Polit & Beck, 2008). In this study, the dependent variable is the level of pain perception in children during intramuscular injection.

Attribute variables

Variable that describes the study sample characteristics are termed as attribute variables (Polit & Beck, 2008). In this study, the attribute variables are the demographic variable proforma of the children and the clinical variable proforma of the children.

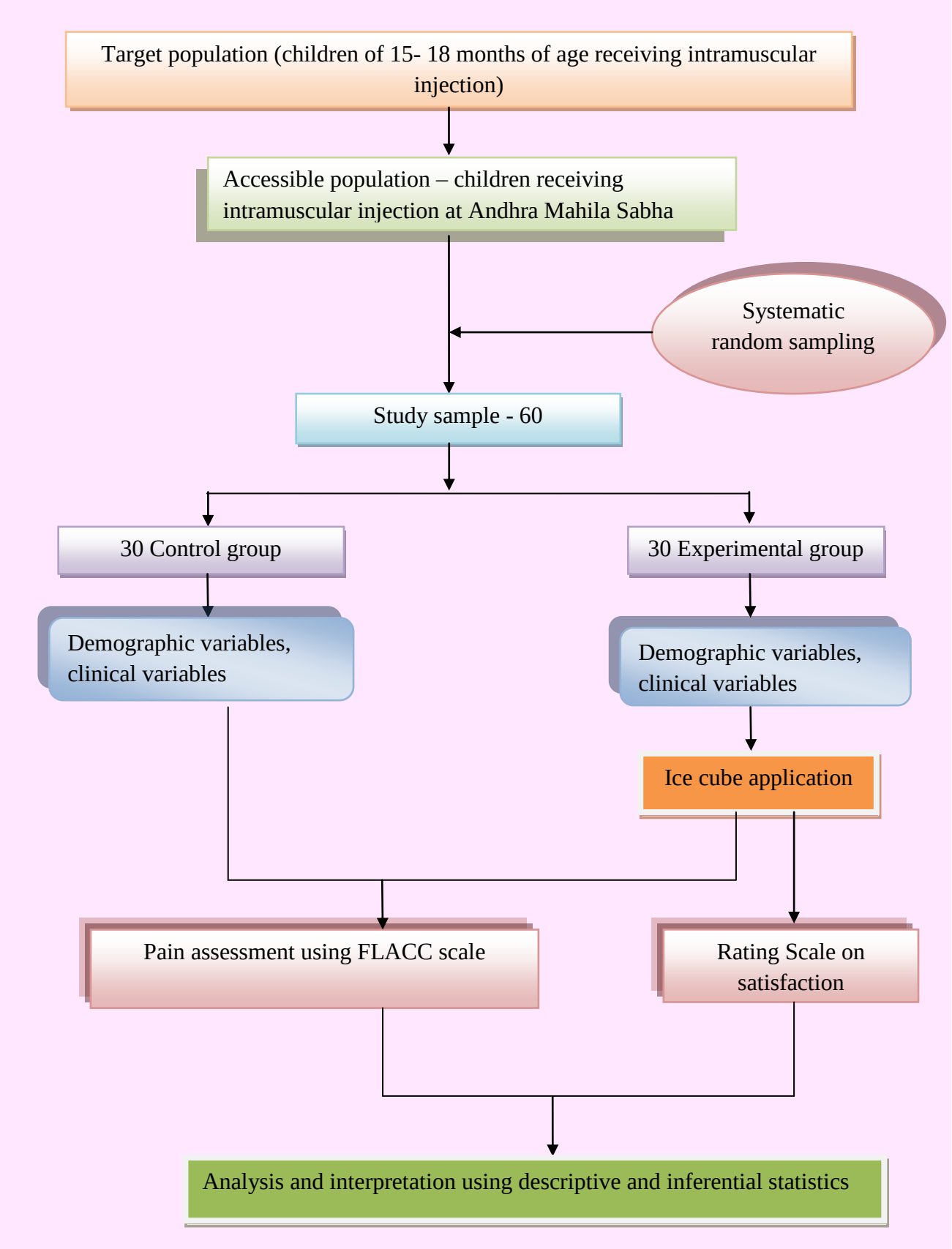

Fig. 2. Schematic Representation of the Research Methodology

Research Setting

Research setting is the physical location and conditions in which data collection takes place in study (Polit and Beck, 2008).

The study was conducted in immunization clinic at Durgabai Deshmukh General Hospital and Research Centre, Andhra Mahila Sabha, Chennai. It is a 100 bedded general hospital with specialization in gynaecology, Pediatric and geriatric care. In this hospital, immunization clinic is conducted every week from Monday to Saturday between 9:00am to 1:00 pm. Around 400 children receive immunization in the hospital every month. Among them about 100 children between 15 to 18 months of age receive either DPT booster, Pentavac, MMR injection.

Population

Population is the entire set of individual or object having some common characteristics (Polit and Beck - 2008).

Target population

The entire population is the aggregate of cases in which a researcher is interested and would like to generalize the study result (Polit and Beck, 2008).

The target population in this study comprises of all children, in the age of 15 to 18 months who receive intra muscular injection

Accessible population

The accessible population is the aggregate of cases that conforms to designated criteria and that are accessible as subject for a study (Polit and Beck, 2008).

The accessible populations in this study were the children between 15 – 18 months of age who received either DPT vaccine or DTPa booster – 1, Hib booster, MMR -1, pentavac at Durgabai Deshmukh General Hospital and Research Centre, Andhra Mahila Sabha, Chennai.

Sample

According to Polit and Beck (2008), the sample is a subset of the population selected to participate in a study.

A sample consists of children receiving intra muscular injection, who meets the inclusion criteria at selected hospital, Chennai is selected for the study.

Sample Size

A sample size of 60 children who meet the inclusion criteria is chosen for this study, in that 30 will taken for control group and 30 will taken for experimental group who satisfy the inclusion criteria.

Sampling Technique

Sampling is the process of selecting a portion of the population to represent the entire population (Polit and Beck 2008).

The participants of the present study will be selected by systematic random sampling technique, in which the children who satisfies the inclusion criteria were selected numbered as one and two. The children who are numbered as one was assigned to control group and two numbers to experimental group

Sampling Criteria

Inclusion criteria

- Both male and female children between 15 – 18 months of age.
- Children receiving either DPT vaccine or DTPa booster -1, Hib booster, MMR-1, Pentavac.
- Caregivers who know Tamil or English.

Exclusion criteria

- Children with any physical illness.
- Mother who are not willing to participate in the study.

Selection and Development of Study Instruments

The study aimed at evaluating the effectiveness of ice cube application upon pain perception of children during intramuscular injection. Data collection instruments were developed through an extensive review of literature and consultation with experts. The instruments used in this study were, Demographic variable Proforma, Clinical variable proforma, FLACC scale for pain assessment, rating scale on satisfaction of the mother regarding ice cube application during intra muscular injection.

Demographic variable proforma for children

Demographic variable proforma of children includes the age in years, gender, type of family, area of residence, family monthly income.

Clinical variable proforma for children

Clinical variable proforma for children includes height, weight, type of injection, previous hospitalization of the child, history of allergic reaction.

FLACC scale for pain assessment

FLACC scale for pain is a standardized scale which was developed by Merkel et al in 1997. It consists of five criteria: face, leg, activity, cry, consolability. Each criterion has scored 0,1 and 2.

Score	Interpretation
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

Rating scale on satisfaction of the mother regarding ice cube application during intramuscular injection

The level of satisfaction of the mother regarding ice cube application during intramuscular injection was measured by rating scale, which comprises of 3 categories: researcher's capacity, effects of intervention felt by mother, effects of intervention in the child. Rating scale includes 10 items. The responses include highly satisfied, satisfied, dissatisfied, highly dissatisfied with the score 3, 2, 1, 0 respectively. The maximum score is 30.

Score	Precentage	Interpretation
<12	< 40%	Low satisfaction
12 - 20	40 - 69%	Moderate satisfaction
21-30	70 -100%	High satisfaction

Psychometric Properties

Validity of study instruments

Content validity is the degree to which an item in an instrument adequately represents the universe of the content (Polit and Beck, 2008).

The tools were given for validation to 7 experts in the field of research and nursing. The validators had suggested some modification in the demographic variable proforma and clinical variable proforma. The modifications and suggestions of experts were incorporated in the final preparation of the tool.

Reliability of the instruments

The reliability is the degree of consistency with which an instrument measures the attribute which is designed to measure (Polit and Beck, 2008).

1. Face Leg Activity Cry Consolability (FLACC) Scale

The reliability of the tool was determined by interrater reliability 0.92 after the procedure for FLACC scale. It was found to be highly reliable.

2. Rating scale on satisfaction of the mother regarding ice cube application during intramuscular injection

The reliability of the tool was tested using the split half method and the reliability was found to be 0.8 which indicate that the tool is highly reliable.

Pilot study

Pilot study is a miniature version of actual study, in which the instrument is administered to the subject drawn from the sample population. It is a small scale version or trial run done in preparation for major study (Polit and Beck – 2008).

The purpose was to find out the feasibility and practicability of the study and to finalize the tool. The pilot study was conducted with 12 children receiving intra muscular injection, among them 6 in control group and 6 in experimental group in Andhra Mahila Sabha, Chennai. On the whole, the intervention was found to be feasible, effective and easy to administer.

Intervention Protocol

In the experimental group, the child was placed in a comfortable position in the mother's lap and a small ice bag is made with the ice cubes and terry wash cloth. The LI- 4 site was identified and ice bag was applied over the area for 30 seconds. It was then repeated in both hands of the children. Once an ice cube application is over, the intramuscular injection was administered. Pain perception of the children was assessed using FLACC scale. The level of satisfaction of the mothers regarding the ice cube application was assessed using a rating scale in the experimental group.

Protection of Human rights

The researcher presented the proposal to the ethical committee of Apollo Hospitals and got ethical clearance to further proceed with the study. The researcher obtained permission to conduct the study from the Principal and Head of the Department of Pediatric Nursing department of Apollo College of nursing and the Medical superintendent of Andhra Mahila Sabha. Informed consent was obtained from parents of children before collecting the data and confidentiality was maintained throughout the study.

Data collection procedure

Data collection is the gathering of information needed to address a research problem (Polit and Beck, 2008). The data was collected from 25-6-2012 to 21-7-2012 at Durgabai Deshmukh General Hospital and Research Centre, Andhra Mahila Sabha, Chennai. After obtaining permission to conduct study from the Medical Superintendent of Andhra Mahila Sabha, the researcher met the head of the pediatric department and got the approval and valuable suggestions to conduct the study. Verbal consent was obtained from participants and their parents.

In this study, children who satisfied the inclusion criteria were selected randomly, and numbered as one and two. The children who were numbered as one were assigned to control group and two numbers to experimental group. The researcher introduced herself to the parents of the children and obtained verbal consent for the study.

The researcher collected the demographic variables and the clinical variables by interviewing the parents and by performing anthropometric measurements. The children in the control group were assessed using a FLACC scale for pain perception after intramuscular injection without any intervention. In the experimental group, ice cube application was given for a period of 30 seconds in LI- 4 acupressure point is, the web between the thumb and index finger of hand before intramuscular injection. At the end of this period, intra muscular injection was given and post assessment of pain was done immediately for 1 minute by using observation check list and FLACC scale. The level of satisfaction of mothers regarding ice cube application was assessed using satisfaction rating scale.

Problem Faced During Data Collection

Few mothers are not willing to participate in the study.

Plan for Data Analysis

Data analysis is a systematic organization and synthesis of research data and testing of research data and testing of research hypothesis by using the obtained data (Polit and Beck, 2008).

The data analysis was carried out by descriptive statistics like frequency distribution, percentage, mean, standard deviation and inferential statistics like ‘t’ test and chi-square.

Summary

This chapter dealt with the research methodology. It includes selection of research approach, research design, setting, population, sample, sampling technique, sampling criteria, selection and development of study instruments, validity and reliability of study instrument, pilot study, data collection procedure and plan for data analysis. In the following chapter, analysis is interpreted using descriptive and inferential statistics.

CHAPTER – IV

ANALYSIS AND INTERPRETATION

This chapter deals with analysis and interpretation of data collected on a number of issues from various sources. Statistics is a field of study concerned with techniques or methods of data collection, classification, summarising, interpretation, drawing inferences, testing of hypothesis and making recommendations (Mahajan, 2004).

Data was collected from 60 mothers of children receiving intramuscular injection at Andra Mahila Sabha, Chennai, among them 30 were in control group and 30 in experimental group to determine the effectiveness of ice cube application prior to intramuscular injection. The data was analysed according to the objectives and hypothesis of the study. The data were analyzed, tabulated and interpreted using descriptive and inferential statistics.

Organisation of the Findings

The findings of the study were organized and presented under the following headings:

- Frequency and percentage distribution of demographic variables in the control and experimental group of children.
- Frequency and percentage distribution of clinical variables in the control and experimental group of children.
- Frequency and percentage distribution of pain perceived by children during intramuscular injection measured by FLACC scale in experimental and control group of children.

- Comparison of mean and standard deviation of pain perception by control and experimental group of children during intramuscular injection measured using FLACC scale.
- Frequency and percentage distribution of level of satisfaction of mothers on ice cube application during intramuscular injection in experimental group of children.
- Association between selected demographic variables and pain perception of infant in control group using FLACC scale.
- Association between selected demographic variables and pain perception of children in experimental group using FLACC scale.
- Association between selected clinical variables and pain perception of children in control group using FLACC scale.
- Association between selected clinical variables and pain perception of children in experimental group using FLACC scale.

Table . 1

Frequency and Percentage Distribution of Demographic Variables in the Control and Experimental Group of Children.

Demographic variables	Control group (n=30)		Experimental group (n=30)	
	n	p	N	p
Age of the child in months				
< 15 months	-	-	-	-
15-16 months	14	46.6	9	30
16-17months	5	16.6	1	3.3
>17 months	11	36.6	20	66.6
Gender of the child				
Male	20	66.6	11	36.6
Female	10	33.4	19	63.3
Type of family				
Nuclear	20	66.6	24	80
Joint	10	33.4	6	20
Extended	-	-	-	-
Religion				
Hindu	21	70	22	73.3
Muslim	3	10	-	-
Christian	6	20	8	26.7
Others, specify	-	-	-	-

The data in table 1 reveals that majority of the children belonged to Hindu religion (70%, 73.3%) significant percentage of the children were males (66.6%, 36.6%), most of the children were in the age group of >17 months (36.6%, 66.6%) in control and experimental group of children respectively.

Fig.3: Shows the percentage distribution of area of residence in control and experimental group of children. Majority of the children (43.3%, 83.3%) resides in urban area in control and experimental group of children respectively.

Fig.4: Reveals that (43.3%, 36.6%) of family income of children in control group and experimental group's family income is between Rs.10001-15000.

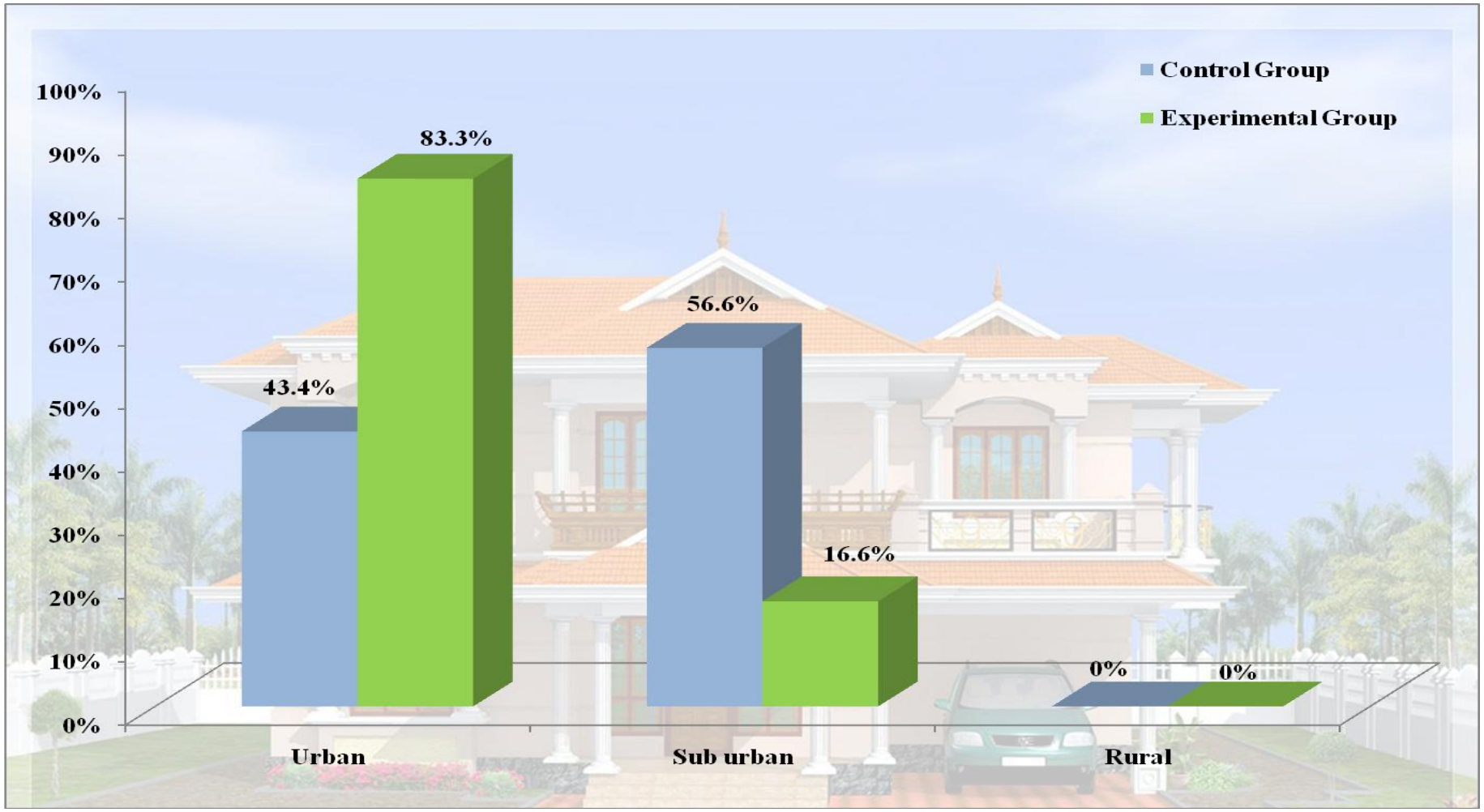

Fig.3: Percentage Distribution of Area of Residence in Control and Experimental Group of Children.

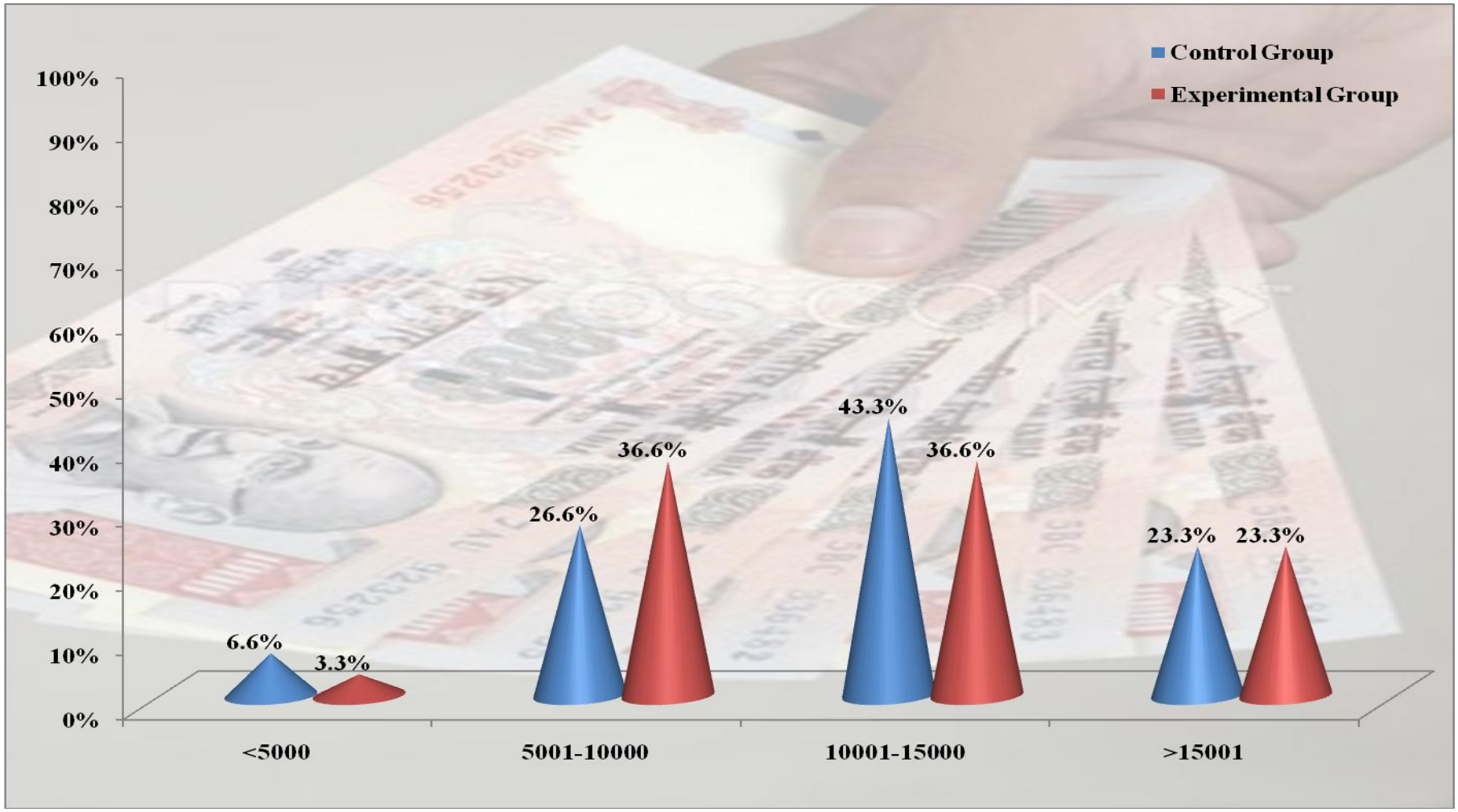

Fig .4: Percentage Distribution of Family Monthly Income in the Control and Experimental Group of Children

Table . 2

Frequency and Percentage Distribution of Clinical Variables in the Control and Experimental Group of Children

Clinical Variables	Control Group (n=30)		Experimental Group (n=30)	
	n	p	N	P
Height of the child in centimeters				
<80	17	56.6	14	46.6
81-85	11	36.6	11	36.6
85-90	2	6.6	5	16.6
>90	-	-	-	-
Weight of the child in kilograms				
<11	17	56.6	15	50
11.1-12	10	33.3	9	30
12.1-13	3	10	5	16.6
>13	-	-	1	3.3
Type of injection				
DPT	-	-	-	-
Pentavac	13	43.3	16	53.3
MMR	15	50	11	36.6
Other	2	6.6	3	10

Previous hospitalization				
Yes	3	10	1	3.3
No	27	90	29	96.6
History of allergic reaction				
Yes	-	-	-	-
No	30	100	30	100

The data presented in table 2 reveals that most of the children (56.6%, 46.6%) were less than 80 centimeters tall, (56.6%, 50%) of children weighed < 11 kilograms, (43.3%,53.3%) received pentavac injection and none of the children had history of allergic reaction in control and experimental group of children respectively.

Table. 3

Frequency and Percentage Distribution of Pain Perceived by Children During Intramuscular Injection Measured by FLACC scale

Pain measured by FLACC / group	No pain		Mild		Moderate		Severe	
	n	p	n	p	N	p	N	P
Control group	-	-	1	3.3	3	10	26	86.6
Experimental group	1	3.3	18	60	11	36.6	-	-

The data presented in the table 3 reveals that majority of children in the control group had moderate and severe pain 86.6% during intramuscular injection, whereas in experimental group 60% of children had mild pain.

Table. 4

Comparison of Mean and Standard Deviation of Pain Perception of Control and Experimental Group of Children During Intramuscular Injection Measured by FLACC scale.

(N=60)

Group	n	M	SD	't' value
Control group	**30**	**7.4**	**1.3**	**11.7*** **
Experimental group	**30**	**3.3**	**1.51**	

***P<0.001

The data in the table 4 depicts that the mean and standard deviation of the control and experimental group of children is 7.4, 1.3; 3.3, 1.51 respectively. The 't' value of 11.7 is highly significant at P< 0.001 level of significance.

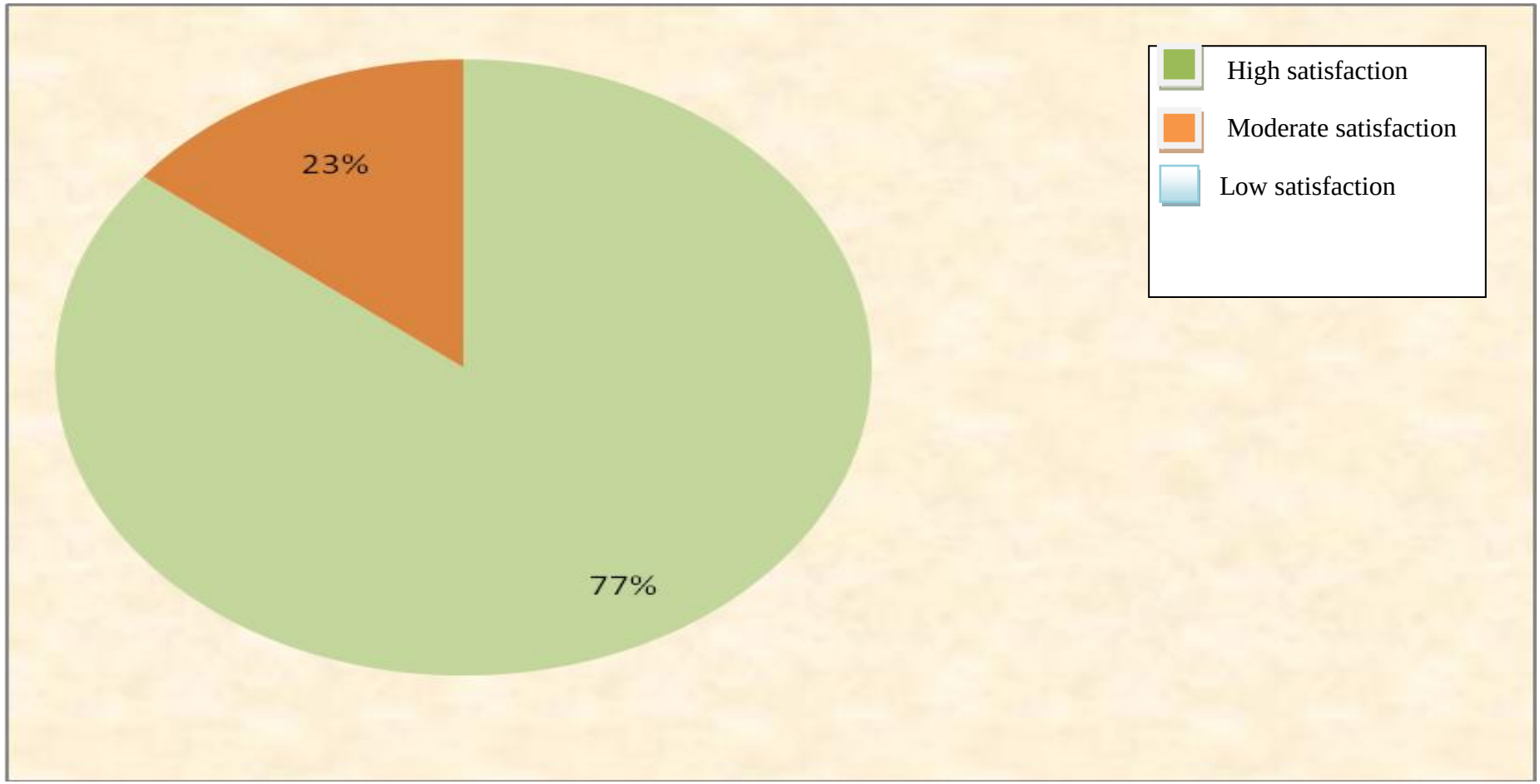

Fig.5 Percentage Distribution of Level of Satisfaction of Mothers on Ice Cube Application to Children During Intramuscular Injection in Experimental Group of Children.

Table . 5

Association between the Selected Demographic Variables and Pain Perception of Children in Control Group using FLACC Scale

(N= 30)

Demographic variables	FLACC score				χ^2
	Upto mean		Above mean		
	N	p	n	P	
Age of the child in months					
Upto 16 months	2	6.6	12	40	0.02
Above 16 months	2	6.6	14	46.6	df=1
Gender of the child					
Male	4	13.3	16	53.3	2.307
Female	0	0	10	33.3	df=1
Type of family					
Nuclear	2	6.6	19	63.3	0.87
Joint	2	6.6	7	23.3	df=1
Religion					
Hindu	3	10	18	60	0.054
Others	1	3.3	8	26.6	df=1
Area of residence					
Urban	1	3.3	13	43.3	0.87
Suburban	3	10	13	43.3	df=1
Family monthly income in rupees Rs.					
Upto 10000	1	3.3	9	30	0.144
Above 10000	3	10	17	56.6	df=1

*p<0.05

From the table 5, it could inferred that there was no significant association between demographic variables and pain perception in control group of children.

Table . 6

Association between the Selected Demographic Variables and Pain Perception of Children in Experimental Group using FLACC Scale

(N= 30)

Demographic variables	FLACC score				χ^2
	Upto mean		Above mean		
	N	p	n	p	
Age of the child months					
Upto 16 months	5	16.6	4	13.3	0.334
Above 16 months	14	46.6	7	23.3	df=1
Gender of the child					
Male	10	33.3	1	3.3	5.68*
Female	9	30	10	33.3	df=1
Type of family					
Nuclear	13	43.3	11	36.6	4.35*
Joint	6	20	0	0	df=1
Religion					
Hindu	13	43.3	9	30	0.639
Others	6	20	2	6.6	df=1
Area of residence					
Urban	17	56.6	8	26.6	1.406
Sub urban	2	3.3	3	10	df=1
Family monthly income in rupees					
Upto 10000	9	30	5	16.6	0.01
Above 10000	10	33.3	6	20	df=1

*P<0.05

From the table 6, it could be inferred that there was a significant association between the gender of the child, type of family and pain perception in the experimental and no significant association between other demographic variables and pain perception in experimental group of children.

Table .7

Association between the Selected Clinical Variables and Pain Perception of Children in Control Group using FLACC Scale

(N= 30)

Clinical variable	FLACC score				
	Upto mean		Above mean		χ^2
	n	p	n	p	
Height of the child in centimeters					
Upto 85	3	10	25	83.3	2.493
Above 85	1	3.3	1	3.3	df=1
Weight of the child in kilograms					
Upto 12	3	10	24	80	1.153
Above 12	1	3.3	2	6.6	df=1
Type of injection					
Pentavac	1	3.3	12	40	0.631
Other	3	10	14	46.6	df=1
Previous hospitalization					
Yes	1	3.3	2	6.6	1.15
No	3	10	24	80	df=1

*p<0.05

From the table 7, it could be inferred that there was no significant association between clinical variables and pain perception in control group of children.

Table. 8

Association between the Selected Clinical Variables and Pain Perception of Children in Experimental Group Using FLACC Scale

(N= 30)

Clinical variable	FLACC score				χ^2
	Upto mean		Above mean		
	n	P	n	p	
Height of the child in centimeters					
Upto 85	18	60	7	23.3	4.85*
Above 85	1	3.3	4	13.3	df=1
Weight of the child in kilograms					
Upto 12	18	60	6	20	7.03**
Above 12	1	3.3	5	16.6	df=1
Type of injection					
Pentavac	10	33.3	6	20	0.1
Others	9	30	5	16.6	df=1
Previous hospitalization					
Yes	0	0	1	3.3	1.78
No	19	63.3	10	33.3	df=1

*p<0.05 **p<0.01

From the table 8, it could be inferred that there was a significant association between the height of the child, weight of the child and pain perception in the experimental and no significant association between other clinical variables and pain perception in experimental group of children.

Summary

This chapter dealt with the analysis and interpretation of the data obtained by researcher. The analysis of the data using descriptive and inferential statistics clearly revealed the effectiveness of ice cube application during intramuscular injection and satisfaction of mothers regarding the intervention. In the following chapter interpretation of the study findings are discussed in detail.

CHAPTER V

DISCUSSION

Statement of the Problem

An Experimental Study to Assess the Effectiveness of Ice Cube Application Upon Pain Perception of Children during Intra Muscular Injection at Andhra Mahila Sabha, Chennai.

The Objectives of the Study were,

1. To assess the level of pain perceived during intra muscular injection by control and experimental group of children.
2. To determine the effectiveness of ice cube application by comparing the pain perception of control and experimental group of children during intra muscular injection.
3. To determine the level of satisfaction of mothers regarding ice cube application during intra muscular injection in the experimental group of children.
4. To find out the association between selected demographic variables and pain perception during intra muscular injection in the control and experimental group of children.
5. To find out the association between selected clinical variables and pain perception during intra muscular injection in the control and experimental group of children.

The study was conducted among 60 infants between 15 – 18 months of age receiving intra muscular injection at Andhra Mahila Sabha, Chennai. The effectiveness

of ice cube application was assessed upon pain perception of children during intramuscular injection.

Demographic variables of children

Majority of the children belonged to Hindu religion (70%, 73.3%) and most of the children were in the age group of >17 months (36.6%, 66.6%), with the family income between Rs.10001- 15000 (43.3%, 36.6%) in control and experimental group of children respectively.

Regarding the gender, majority (66.66%) were males in control group and in experimental group 36.66% were males and 63.33% were females. Findings confirmed that sex ratio over the decades in India has been deteriorating. The 2011 census report showed the sex ratio in India is 940 females /1000 males which are inconsistent with the obtained date.

Considering the area of living in control group 56.66% of children reside in a suburban area and in experimental group 83.33% of children reside in urban areas. India has 641,000 inhabited villages and 72.2 percent of the total population resides in these rural areas.

Clinical variables of children

Most of the children in control group 56.66% and in experimental group 46.66% are under <80 centimeter height. About 36.66% of children height is between 81 – 85 centimeter in control and experimental group. Only 6.66% in control group and 16.66% in experimental group of children height is between 85 -90 centimeters.

56.66% of children in control group and 50% of children in experimental group weight < 11 kilogram. About 33.33% in control group and 30% in experimental group weight between 11.1 – 12 kilogram. Only 10% of children in control group and 16.66% of children in experimental group weight between 12.1 – 13 kilogram.

50% of children in control group children received MMR injection and 53.3% of children in experimental group children received pentavac injection. The findings depites that care givers are aware about the new trends of combined vaccination which prevent multiple injection which may increase the stress in children.

It is a noticeable fact that 90% of children in control group and 96.66% of children in experimental group did not have any previous hospitalization. Only 10% in control group and 3.33% of children in experimental group had previous history of hospitalization. It's a remarkable finding that all the children in control and experimental group did not have any allergic reaction to any drugs.

The first objective of the study was to assess the level of pain perceived during intra muscular injection by control and experimental group of children

The level of pain perceived by children after intramuscular injection in control and experimental group was measured by using FLACC scale. Majority of the children in control group had severe pain (86.66%) where as in experimental group (60%) had mild pain.

The health care provider should accommodate for the patient's comfort, safety, age, activity level, and the site of administration when considering patient positioning

and restraint. The parent should be encouraged to hold the child during administration. Parent participation has been shown to increase the child's comfort. The parent/guardian should be instructed on how to help the child stay still so the vaccine can be administered safely. If the parent is uncomfortable, another person may assist or the patient may be positioned safely on an examination table. It reduces the stress in children and gives a secure feeling.

The pain perception of children was assessed using Face Leg Activity Cry Consolability Scale (FLACC) in both control and experimental group of children. The mean and standard deviation of pain score in control group is M=7.4, SD=1.3 and that of experimental group is M=3.3, SD= 1.51 which indicate experimental group had lower level of pain perception in comparison with control group.

Painful stimulation occurs due to intramuscular injection is unavoidable. But the transmission of the stimuli can be blocked by various distraction techniques in children. As one of the measures, the children in the experimental group were applied ice cubes in LI-4 acupressure site before administration of injections and the findings revealed that the pain perception is reduced in children when compared to the control group of children.

Holbert (2006) conducted a study to assess the effectiveness using pressure to decrease pain during intramuscular injections. The purpose of this study was to determine if applying pressure to the site for 10 Sec prior to an intramuscular injection would reduce injection pain, an approach suggested by anecdotal observation and the gate control theory. The subjects were 93 children who had vastus lateralis

intramuscular injections of immune globulin at a county health department. Forty-eight received the pressure treatment at acupressure site and 45 received a standard injection in which no pressure was applied. Mean pain intensity on a 100-mm visual analogue scale, adjusted for differences in injection volume, was 13.6 mm for the experimental group and 21.5 mm for the control group (P = 0.03). The findings suggest that simple manual pressure applied to the site is a useful technique to decrease injection pain.

The second objective of the study was to determine the effectiveness of ice cube application by comparing the pain perception of control and experimental group of children during intra muscular injection.

The effectiveness of ice cube application upon pain perception among the experimental group of children during intra muscular injection was assessed statistically using the independent‘t’ test. The mean and standard deviation of pain score was lower in experimental group (M=3.3, SD= 1.51) of who received ice cube application before intra muscular injection when compared to the control group of children (M=7.4, SD=1.3). The difference was statistically significant at P<0.001, the ‘t’ value was 11.71. The result could be attributed to the effectiveness of ice cube application upon pain perception of children during intramuscular injection.

Application of ice cubes which stimulates the large diameter sensory fibers that synapse in the dorsal horn of the spinal cord which produces an inhibitory effect on the transmission of incoming pain signal, from the small diameter sensory fibers stimulated by needle puncture, causes fewer pain signal to reach the brain and reducing perception of it and hence the child's perception of pain has reduced. Hence, the null hypothesis

$H_{01,}$ there will be no significant difference in pain perception during intra muscular injection among control and experimental group of children was rejected.

The researcher concluded that the findings must be disseminated so that evidence based knowledge can be utilized in the clinical setting to reduce the pain perception of children during intra muscular injection.

The third objective of the study was to determine the level of satisfaction of mothers regarding ice cube application during intra muscular injection in the experimental group of children.

The level of satisfaction of mothers regarding ice cube application prior to intra muscular injection, is noted that, majority of the mothers (77%) were highly satisfied and only (23%) of the mothers are moderately satisfied. It indicates that the mothers were also under stress and anxious regarding the painful experience of infant during the intra muscular injections. The effective pain management measure which is safe simple cost effective and easier to administer help the mothers to have higher levels of satisfaction. These findings can be disseminated to the nursing superintendent of the hospital to implement the cost effective pain reduction intervention in the hospital.

The fourth objective of the study was to find out the association between selected demographic variables and pain perception during intra muscular injection in the control and experimental group of children.

Chi-square test is used to find out the association between the selected demographic variable and the pain perception of children. There was no significant

association between selected demographic variables like age, gender, type of family area of residence, family monthly income and pain perception at $p<0.05$ in control group.

For children undergoing vaccination, there is sufficient evidence for or against the use of skin-cooling techniques (vapocoolants, ice cubes, cool/cold packs) to reduce pain at the time of injection. Some vaccines can be administered intramuscularly or subcutaneously, although the manufacturer's instructions generally recommend only one route of administration. Two randomize control trail and one study with quasi-experimental design, with a total of 817 children (14 months to 10 years), were included in the systematic review. In two of the studies, no differences were observed in terms of either observer-rated pain in children's self-reported pain. In one study, intramuscular injection caused more pain than subcutaneous injection in infants and children. However, the investigators did not provide details about the injection technique used (e.g., whether the intramuscular injections were performed by aspiration), which could have a substantial impact on perception of pain.

There was a significant association between the gender of the child (χ^2 =5.68, df=1), type of family (χ^2 =4.35, df=1) and pain perception at $p<0.05$ in the experimental group and no significant association between other demographic variables like age, area of residence, family monthly income and pain perception in the experimental group of children. Hence the null hypothesis H_{02} was partially rejected with regard to the gender of the child and type of family in experimental group of children and partially retained with regard to other demographic variables in control and experimental group of children.

The fifth objective of the study was to find out the association between selected clinical variables and pain perception during intra muscular injection in the control and experimental group of children

Chi square test is used to find out the association between the selected clinical variable and the pain perception of children. There was no significant association between selected clinical variables like height,weight, type of injection, previous hospitalization and pain perception at $p<0.05$ in control group.

All the children received the combined vaccine and hence the association between the type of injection and pain perception was not identified. Damage to the tissue will definitely cause painful stimuli. Previous history of hospitalization does not influence the pain perception. Thus irrespective of the clinical variable all the children had same pain perception. Hence it is necessary to provide pain reducing intervention to all the children receiving intramuscular injection.

There was a significant association between the height of the child (χ^2 =4.85, df=1), weight of the child (χ^2 =7.03, df=1) and pain perception at $p<0.05$ in the experimental group of children and no significant association between other clinical variables and pain perception in experimental group of children. Hence, the null hypothesis H_{03} was partially rejected with height and weight of the children in experimental group and partially retained with regard to other clinical variables in control and experimental group of children.

Researcher concludes that ice cube application can be followed as a non pharmacological pain intervention during intra muscular injection for children in the

hospital as it is simple, safe, cost effective and easier to administer. The finding can be disseminated as evidence based practice and the effectiveness can be implicated in nursing education.

Summary

This chapter dealt with the objectives of the study, major finding such as the demographic variables and clinical variables of children, mean and standard deviation of pain score in control and experimental group of children, association between the selected demographic variable and clinical variable and the pain perception in children and level of satisfaction of mothers on ice cube application during intra muscular injection.

CHAPTER VI

SUMMARY, CONCLUSION, IMPLICATION AND RECOMMENDATION

The heart of the research project lies in reporting the findings. This is the most creative and demanding part of the study. This chapter gives a brief account of present study including the conclusion drawn from the findings, nursing implication of the study and recommendations.

Summary

The present study was indented to analyze the effectiveness of ice cube application upon pain perception of infant during intramuscular injection at selected hospitals, Chennai.

Objectives of the study

1. To assess the level of pain perceived during intra muscular injection by control and experimental group of children.
2. To determine the effectiveness of ice cube application by comparing the pain perception of control and experimental group of children during intra muscular injection.
3. To determine the level of satisfaction of mothers regarding ice cube application during intra muscular injection in the experimental group of children.
4. To find out the association between selected demographic variables and pain perception during intra muscular injection in the control and experimental group of children.

5. To find out the association between selected clinical variables and pain perception during intra muscular injection in the control and experimental group of children.

Null hypothesis

H_{01}: There will be no significant difference in pain perception during intra muscular injection among control and experimental group of children.

H_{02}: There will be no significant association between selected demographic variable and pain perception during intra muscular injection in the control and experimental group of children.

H_{03}: There will be no significant association between selected clinical variable and pain perception during intra muscular injection in the control and experimental group of children.

The conceptual frame work for the study was developed on the basis of Roy's adaptation model, which was modified for the present study. An intensive review of literature and expert guidance laid the foundation to development of tools such as demographic variable proforma, clinical variable proforma, FLACC scale and mother's satisfaction rating scale to assess the level of satisfaction.

An experimental research approach with post test only design was adopted for the study. The present study was conducted at Durgabai Deshmukh General Hospital and Research Centre, Andra Mahila Sabha, Chennai among the children receiving intramuscular injection. The study sample size was 60 children selected by systemic

random sampling technique of which 30 were assigned to control group and 30 to the experimental group.

The investigator used the demographic variable proforma, clinical variable proforma to obtain base line data. FLACC scale was used to assess the pain perception of children and rating scale to assess the level of satisfaction of mothers. The data collection tools were validated and reliability was established. After pilot study, the data collection of main study was conducted for 4 weeks. The collected data was tabulated and analysed by using appropriate descriptive and inferential statistics.

The major findings of the study

Demographic variables

Majority of the children belonged to Hindu religion (70%, 73.3%) and living in urban area (43.3%, 83.3%), significant percentage of the children were males (66.6%, 36.6%), most of the children were in the age group of >17 months (36.6%, 66.6%), with the family income between Rs.10001- 15000 (43.3%, 36.6%) in control and experimental group of children respectively.

Clinical variables

Most of the children (56.6%, 46.6%) were less than 80 centimeters tall, (56.6%, 50%) of children weighed < 11 kilograms, (43.3%,53.3%) received pentavac injection and none of the children had history of allergic reaction in control and experimental group of children respectively.

Comparing of mean and standard deviation of pain perception by control and experimental group of children

The mean and standard deviation of pain perception of children in the control group was Mean=7.4, SD=1.3 and in experimental group Mean=3.3, SD=1.51 respectively. The 't' value of 11.7 was highly significant at P< 0.001 level of significance. Thus the null hypothesis H01 there will be no significant difference in pain perception during intra muscular injection among control and experimental group of children was rejected.

Association between the selected demographic variable and pain perception of children in control group and experimental group using FLACC scale

There was no significant association between selected demographic variables and pain perception at $p<0.05$ in control group of children. There was a significant association between the gender of the child (χ^2 =5.68, df=1), type of family (χ^2 =4.35, df=1) and pain perception at $p<0.05$ in the experimental group and no significant association between other demographic variables and pain perception in the experimental group of children. Hence the null hypothesis H_{02} was partially rejected with regard to the gender of the child and type of family in experimental group of children and partially retained with regard to other demographic variables in control and experimental group of children.

Association between the selected clinical variable and pain perception of children in control group and experimental group using FLACC scale

There was no significant association between selected clinical variables and pain perception in control group of children. There was a significant association between the height of the child (χ^2 =4.85, df=1), weight of the child (χ^2 =7.03, df=1) and pain perception at $p<0.05$ in the experimental group of children and no significant association between other clinical variables and pain perception in experimental group of children. Hence, the null hypothesis H_{03} was partially rejected with height and weight of the children in experimental group and partially retained with regard to other clinical variables in control and experimental group of children.

Level of satisfaction of mothers on ice cube application to children during intramuscular injection in experimental group of children

The study findings reveals that majority (77%) of the mothers were highly satisfied and (23%) of the mothers were moderately satisfied regarding the ice cube application during intramuscular injection. The intervention also enhanced the perception and confidence among the mothers to support the child in reducing the pain experiencing during intramuscular injection.

Conclusion

The intramuscular injection is a stressful event for children, it is necessary to provide pharmacological or non pharmacological intervention to reduce the pain and discomfort in children. The findings of the study indicated that the ice cube application is simple, safe, cost effective and easy to administer than any other pharmacological

pain intervention. So it must be incorporated in clinical setting as a pain intervention measures.

Implications

The findings of the study have implications in the different branches of nursing profession i.e, nursing practice, nursing education, nursing administration and nursing research. By assessing the effectiveness of ice cube application during intramuscular injection, we get a clear picture regarding different steps to be taken in all fields, to improve the standards of nursing profession.

Nursing practice

As intramuscular is the common route for administration of immunization and is a painful procedure from birth, pain management is very essential. As it was identified from the study findings the ice cube application was an effective pain management during intramuscular injection. As nurses play a major role in identifying the health need of children, they should have awareness about the simple pain management intervention, to relieve pain and discomfort of the children during injections. All institutions and clinics should be supported and encouraged this kind of non pharmacological measures during injections.

Nursing education

Integration of theory and practice is a vital need and it is important in nursing education. Care of children has been included since the beginning years of nursing education. The focus on measures nursing education must focus on innovation to

enhance nursing care. Some research suggests that ice cube application is a non pharmacological measure to reduce pain. The research findings suggest that the ice cube application is simple, safe, cost effective and easy to administer than any other pharmacological pain intervention. So it must be incorporated in clinical setting as a pain intervention measures. Nursing education curriculum should be incorporated with emphasis on non pharmacological measures to reduce the pain perception of children during hospital stay. The nursing students should be taught about the importance of various pain relief measures that could implemented in care of children.

Nursing administration

With technological advances and every growing challenge of health care needs, the administration has a responsibility to provide nurses with substantive confined education opportunities. This will enable the nurses to update their knowledge on latest pain management strategies available to demonstrate high quality care. Periodic formal training program for nurses on pharmacological and non pharmacological pain management measures. Nurse administrators can arrange conferences, in service education and workshop to encourage staff nurse to learn about various alternative and complimentary therapies used as pain relief strategies.

Nursing research

In India, evidence based clinical strategies are not sufficient. As there are fewer studies related to pain intervention during injection there is a need for extensive and intensive studies in this area. Nurse researcher should challenge to perform scientific work and take part in assessment, applications, evaluation of a child during

intramuscular injection. Researchers must focus on various aspects and develop appropriate tools for pain assessments in children during injection. It opens the large avenue for research. Since ice cube application can be implemented to children who receives intra muscular injection and its effectiveness can be tested through research. Dissemination of the findings of evidence based practice through conferences, seminars, publications in national and international nursing journals and World Wide Web will benefit a wider community.

Recommendations

- The study can be conducted on larger sample to generalize the results.
- The study can be conducted in different settings
- The study can be conducted for pain management during other invasive procedures.
- A comparative study can be conducted to evaluate the effectiveness of various other interventions to reduce pain.
- The study can be conducted among children of different age groups.
- A comparative study can be conducted to assess the effectiveness of ice cube application with other intervention like Emla cream application during intramuscular injection.

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APPENDIX I

LETTER SEEKING PERMISSION TO CONDUCT THE STUDY

Dr Sundhara Medical
Secretary
12/6/12.

Apollo College of Nursing
(Recognised by the Indian Nursing Council and Affiliated to the Tamil Nadu Dr. M.G.R. Medical University, Chennai)

CO/0242/12 **11.06.12**

To

The Medical superintendent,
Andra Mahila Sabha,
Durgabai Deshmukh General Hospital and research centre,
No.11, Dr. Durgabai Deshmukh road,
Raja Annamali Puram
Chennai – 600 028.

Respected Sir / Madam,

Sub.: To request permission for research study – Reg.

Greetings! As part of the curriculum requirement our 2nd year M. Sc. (N) student Ms. Joselin Annabel P.C has selected the following title for her research study.

"An experimental study to assess the effectiveness of ice cube application upon pain perception of children during Intra Muscular injection at selected hospital, Chennai."

So I kindly request your goodselves to permit her to conduct study in your esteemed institution.

Thanking You,

Latha

Dr. LATHA VENKATESAN

PRINCIPAL

IS/ISO 9001:2000

Vanagaram to Ambattur Main Road, Ayanambakkam, Chennai - 600 095.
Ph. : 044 - 2653 4387 Tele fax : 044 - 2653 4923 / 044- 2653 4386

APPENDIX II

LETTER PERMITTING TO CONDUCT STUDY

ANDHRA MAHILA SABHA
DURGABAI DESHMUKH GENERAL HOSPITAL & RESEARCH CENTRE
ISO 9001 : 2000 Certified Hospital

Late Dr. Smt. Durgabai Deshmukh
Founder President
Smt. Rajalakshmi Sunkavally
President
Smt. Sarojini Ramaswamy
Vice-President

Dr. Rathina Sabapathy
Chairman
Smt. I. Lakshmi Murthy
Secretary
Dr. Mrs. ~~Bela Surykumar~~ N.GOMATHY
Medical Superintendent

To
The Principal
Apollo College of Nursing
Vanagaram to Ambattur Main Road,
Ayanambakkam ,
Chennai-600095

20.07.12

Madam,

Ref: Your Letter No.CO/0269/12 Dated: 11.06.12

The Secretary of the Durgabai Deshmukh General Hospital Research Centre Andhra Mahila Sabha is please to permit Ms.Joselin Annabel M.Sc Nursing IIND Year Student of your college to conduct research study in this hospital without determent to the normal function of the department. She has completed her project work from 12-06-2012 to 21-07-2012.

She conducted her project work in an excellent manner with good dedications and punctual timing and in present way.

We offer our best wishes to her for very successful and fruitful career .

Thanking you,

Your's truly
For Durgabai Deshmukh General Hospital &Research Centre

DR.N.GOMATHY
MEDICAL SUPERINTENDENT

No. 11, Dr. Durgabai Deshmukh Road, Raja Annamalai Puram, Chennai - 600 028.
Phone : 2493 8311 Fax : ~~24617611~~ 24611384 E-mail : ddghrc@sify.com ddghrc@hotmail.com

APPENDIX III

ETHICAL COMMITTEE CLEARANCE LETTER

Ethics Committee

Apollo HOSPITALS
TOUCHING LIVES

30th August 2012

To,

Ms. Joselin Annabel P. C,
2nd Year M.Sc (Nursing),
Department of Child Health Nursing,
Apollo College of Nursing,
Chennai.

Ref: An experimental study to assess the effectiveness of ice cube application upon pain perception of children during intra muscular injection at selected hospitals, Chennai.

Sub: Approval of the above referenced project and its related documents.

Dear Ms. Joselin Annabel P. C,

Ethics Committee-Apollo Hospitals has received the following document submitted by you related to the conduct of the above-referenced study.

- Project proposal.
- Participant Consent Form.

The Ethics Committee-Apollo Hospitals reviewed and discussed the study proposal documents submitted by you related to the conduct of the above referenced study at its meeting held on 29th August 2012.

The following Ethics Committee Members were present at the meeting held on 29th August 2012.

Name	Profession	Position in the committee
Mr. S. S. Narayanan	Ethicist	Chairman
Dr. Rema Menon	Clinician	Member Secretary
Dr. Radha Rajagopalan	Clinician	EC-Member
Dr. Krishnakumar	Clinician	EC-Member

Apollo Hospitals Enterprise Limited
21, Greams Lane, Off Greams Road, Chennai - 600 006
Tel : 91 - 44 - 2829 3333 Extn : 6008, 91 - 44 - 2829 5465 Extn : 6639 Fax : 91 - 44 - 2829 4449
E - Mail : ecapollochennai@gmail.com

Ethics Committee

Apollo HOSPITALS
TOUCHING LIVES

Dr. Vijaya Kumar	Clinician	EC-Member
Dr. Clive Fernandes	Consultant Clinical Pharmacologist	Basic Medical Scientist
Dr. Nalini Roa	Social Worker	EC-Member
Ms. N. Suseela	Retired English Teacher	Layperson
Ms. Maimoona Badsha	Lawyer	Lawyer
Dr. Paul Dilipkumar	Clinician	EC-Member
Dr. V. Balaji	Clinician	EC-Member
Dr. M. A. Raja	Consultant Medical Oncologist	EC-Member

After due ethical and scientific consideration, the Ethics Committee has approved the above presentation submitted by you.

The EC review and approval of the report is only to meet their academic requirement and will not amount to any approval of their conclusions/recommendations as conclusive, deserving adoption and implementation, in any form, in any health care institution.

The Ethics Committee is constituted and works as per ICH-GCP, ICMR and revised Schedule Y guidelines.

With Regards,

Rema Menon

Dr. Rema Menon,
Ethics Committee-Member Secretary,
Apollo Hospitals, Chennai,
Tamil Nadu, India.

Dr. REMA MENON
MEMBER SECRETARY
ETHICS COMMITTEE, APOLLO HOSPITALS
APOLLO HOSPITALS ENTERPRISE LIMITED
CHENNAI-600 006, TAMILNADU

30/8/12
Date:

Apollo Hospitals Enterprise Limited
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APPENDIX IV

LETTER SEEKING PERMISSION FOR CONTENT VALIDITY

From

Ms. Joselin Annabel P.C
M.Sc (Nursing) Second Year,
Apollo College of Nursing,
Chennai – 600 095.

To

Dr. Latha Venkatesan,
Principal,
Apollo College of Nursing.

Sub: **Requesting for opinions and suggestions of experts for establishing content validity for research tool.**

Respected Madam,

I am a postgraduate student of the Apollo College of Nursing. I have selected the below mentioned topic for research project to be submitted to The Tamil Nadu Dr. M.G.R Medical University, Chennai as a partial fulfillment of Masters of Nursing Degree

TITLE OF THE TOPIC

An Experimental Study to Assess the Effectiveness of Ice Cube Application Upon Pain Perception of Children during Intra Muscular Injection at Selected Hospital, Chennai.

With regards may I kindly request you to validate my tool for its appropriateness and relevancy. I am enclosing the Background, Need for the study, Statement of the problem, Objectives of the study, Demographic Variable Proforma, Clinical Variable Proforma, satisfactory rating scale for mothers. I would be highly obliged and remain thankful for your great help if you could validate and send it as soon as possible.

Thanking you,

Date: **Yours sincerely,**

Place: **(Joselin Annabel P.C)**

APPENDIX V

LIST OF EXPERTS

1. **Dr. Latha Venkatesan, M.Sc(N), M.Phil (N)., Ph.D (N),**

   Principal and Professor in Maternity Nursing,

   Apollo College of Nursing,

   Chennai- 600 095

2. **Prof. Lizy Sonia. A, M.Sc (N)., Ph.D (N),**

   Vice Principal and Professor in Medical Surgical Nursing,

   Apollo College of Nursing,

   Chennai-600 095

3. **Prof. K. Vijayalakshmi, M.Sc (N)., Ph.D (N),**

   Professor in Psychiatric Nursing,

   Apollo College of Nursing,

   Chennai- 600 095

4. **Prof. Shobana, M.Sc (N),**

   Professor in Community Health Nursing,

   Apollo College of Nursing,

   Chennai- 600 095

5. **Mrs. Nesa Sathya Satchi, M.Sc(N),**

   Reader in Pediatric Nursing,

   Apollo College of Nursing,

   Chennai- 600 095

6. **Mrs. Jaslina Gnana Rani .J, M.Sc (N),**

   Reader in Medical Surgical Nursing,

   Apollo College of Nursing,

   Chennai- 600 095

7. **Mrs. Sasi Kala, M.Sc(N),**

   Reader in Medical Surgical Nursing

   Apollo College Of Nursing

   Chennai-600 095

8. **Mrs. Cecelia Mary M.Sc (N).,**

   Reader in Child Health Nursing,

   Apollo College of Nursing,

   Chennai-600 095

9. **Mrs. Kasthuri, M.Sc (N),**

   Lecturer in Medical Surgical Nursing,

   Apollo College of Nursing,

   Chennai- 600 095

APPENDIX VI

CERTIFICATE FOR CONTENT VALIDITY TO WHOMSOEVER IT MAY CONCERN

This is to certify that the tools and content for the research study developed by II year M.Sc. (Nursing) student of Apollo College of Nursing for her dissertation "An Experimental Study to Assess the Effectiveness of Ice Cube Application Upon Pain Perception of Children during Intra Muscular Injection at Selected Hospital, Chennai." was validated.

Signature of the Expert

APPENDIX VII

CERTIFICATE FOR ACUPRESSURE TRAINING

Institute Of Alternative And Complimentary Therapy

Affiliated of Dr. Vijay's Health Science and Research Foundation

Chennai, India

S.No: Sp.-1020/12

ID No: E.V.K./004/2012

Awards this

Certificate of Attendance

To

Ms.Joselin Annabel.P.C student of M.Sc.Nursing from Apollo College of Nursing, Chennai-95, has done her training in **Acupressure** for one week in our institute.

The Project work entitled " *An Experimental Study to Assess the Effectiveness of Ice Cube Application upon pain Perception of Children during Intra muscular Injection at selected Hospital, Chennai.*"

Given this 6th day of June, 2012 , Chennai

E.V.K.

Lecturer

Course Director

E.V.K.

Dr.E.VIJAYAKUMAR, MPT(Ortho).,MD(Acu).,DYT.,FIMT.,MIAP.

President/Founder

Institute Of Alternative And Complimentary Therapy
Affiliated to Dr. Vijay's Health Science and Research Foundation
Chennai, India

Date: 06.06.2012

Whomsoever may be concern

This is to certify that **Ms.Joselin Annabel.P.C** student of M.Sc.Nursing from Apollo College of Nursing, Chennai-95, has done her training in **Acupressure** for one week in our institute. The Project work entitled *"An Experimental Study to Assess the Effectiveness of Ice Cube Application upon pain Perception of Children during Intra muscular Injection at selected Hospital, Chennai."* During that period, she had been trained in that topic, she acquitted herself well.. She was prompt in her duty and her conduct has been good.

INSTITUTE OF ALTERNATIVE AND COMPLIMENTARY THERAPY Since 2005

Dr.E.VijayaKumar., MPT., MD(Acu)., MIAP., DYT., FIMT

Address: 42/3, G.N.G Street, Varadharajapuram, Amabttur, Chennai -53, Mobile: +91 99406 79698

APPENDIX VIII

RESEARCH PARTICIPANT CONSENT FORM

Dear participant,

I am a M.Sc., Nursing student of Apollo College of Nursing, Chennai. As part of my study, a research on "Effectiveness of Ice Cube Application Upon Pain Perception of Children During Intra Muscular Injection". The findings of the study will be helpful in reducing the pain perception in children.

I hereby seek your consent and co-operation to participate in the study. Please be frank and honest in your responses. The information collected will be kept confidential and anonymity will be maintained.

Signature of the researcher

I ……. Hereby consent to participate and undergo the study

Place:

Date:

Signature of the participant

ஆராய்ச்சியில் பங்கு பெறுவோருக்கான ஒப்புதல் படிவம்

அன்பிற்குரிய பங்கு பெறுவோரே!

ஜோஸ்லின் அன்னபெல்.ப.கி எனும் நான் ,அப்பொலோ செவிலியர் கல்லூரியின் இரண்டாம் படிப்பின் ஒரு பகுதியாக, குழந்தைகளுக்கு தசை ஊசியின் போது வலி உணர்வு மீது பனிக்கட்டி பயன்பாடு பற்றி ஓர் ஆய்வு செய்ய உள்ளேன். இவ்வாய்வு முதியோர்களின் உயர் இரத்த அழுத்ததை குறைக்க பெரிதும்பயன்படும்.

இவ்வாய்வில் தாங்கள் கலந்து கொண்டு தங்களின் பதில்களை உண்மையாகவும், வெளிப்படையாகவும் கூறுமாறு தங்களை தாழ்மையுடன் கேட்டுக் கொள்கிறேன். தங்களின் பதில்கள் இரகசியமாக பாதுகாக்ப்படும் என உறுதியளிக்கிறேன்.

ஆய்வாளரின் கையொப்பம்

_____ எனும் நான் இவ்வாய்வில் கலந்துகொள்ள சம்மதிக்கிறேன்.

இடம் :

தேதி :

பங்கு பெறுவோரின் கையொப்பம்

APPENDIX IX

CERTIFICATE FOR ENGLISH EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation **"An Experimental Study to Assess the Effectiveness of Ice Cube Application Upon Pain Perception of Children during Intra Muscular Injection at Andhra Mahila Sabha, Chennai."** by Ms. Joselin Annabel P.C, II year M.Sc (N), Apollo College of Nursing was edited for English Language appropriateness by Prof. J. GIFTLIN IYADURAI

Signature

J. GIFTLIN IYADURAI M.A.,M.Phil.,
Assistant Professor of English
NM Christian College,
Marthandam - 629 65

APPENDIX X

CERTIFICATE FOR TAMIL EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation **"An Experimental Study to Assess the Effectiveness of Ice Cube Application Upon Pain Perception of Children during Intra Muscular Injection at Andhra Mahila Sabha, Chennai."** by Ms. Joselin Annabel P.C, II year M.Sc (N), Apollo College of Nursing was edited for Tamil Language appropriateness by Dr. I. Makizh Ulda Kamalam

Signature

Dr I. Makizh Ulda Kamalam,
M.A.,M Phil.,Ph.D
Associate Professor
H.O.D of Tamil
N.M. Christian College
Marthandam, K.K. Dist - 629 165

APPENDIX XI

PLAGIARISM DETECTOR ORIGINALITY REPORT

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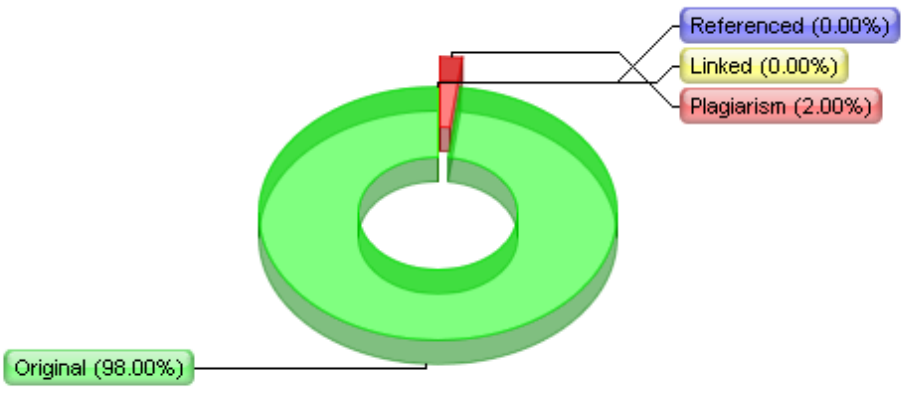

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Referenced 0% / Linked 0%

Original - 98% / 2% - Plagiarism

APPENDIX XII

DEMOGRAPHIC VARIABLE PROFORMA

Purposes

This proforma is used by the researcher to collect information on the demographic variables of children such as age, gender, monthly family income, religion, type of family and area of residence. The information collected will be kept confidential.

Instructions

The researcher will collect the information by interviewing the mother.

Sample number:-

1. **Age of the child**

   1.1 < 15 months ☐

   1.2 15-16 months ☐

   1.3 16-17 months ☐

   1.4 >17 months ☐

2. **Gender of the child**

   2.1 Male ☐

   2.2 Female ☐

3. **Type of family**

   3.1 Nuclear ☐

   3.2 Joint ☐

   3.3 Extended ☐

4. Religion

4.1 Hindu ☐

4.2 Muslim ☐

4.3 Christian ☐

4.4 Others, specify

5. Area of residence

5.1 Urban ☐

5.2 sub urban ☐

5.3 Rural ☐

6. Family monthly income in rupees

6.1 < 5000 ☐

6.2 5001- 10000 ☐

6.3 10001- 15000 ☐

6.4 >15001 ☐

சமுக மற்றும் குடும்ப விவரங்களின் மாதிரிப் படிவம்

நோக்கம்

இந்த மாதிரிப்படிவம் குழந்தையின் மாறுபட்டக் குறிப்புகளாக வயது, பால், மதம், குடும்ப வகை, வீடு உள்ள இடம், குடும்பத்தின் மாத வருமானம் போன்ற மாறு பட்டக் குறிப்புகளை அறிய ஆய்வாளர் பயன்படுத்துவது.

அறிவுரை

தாயிடம் நேர்க்காணல் மூலம் ஆய்வாளர் தகவல்களைச் சேகரிப்பார்.

மாதிரி எண் :

1. குழந்தையின் வயது

1.1 < 15 மாதங்கள் ☐

1.2 15 -16 மாதங்கள் ☐

1.3 16 - 17 மாதங்கள் ☐

1.4 > 17 மாதங்கள் ☐

2 . குழந்தையின் பாலினம்

2.1 ஆண் ☐

2.2 பெண் ☐

3 . குடும்ப வகை

3.1 தனிக் குடும்பம் ☐

3.2 கூட்டுக் குடும்பம் ☐

3.3 விரிவாக்கப்பட்ட குடும்பம் ☐

4 . மதம்

4.1 இந்து மதம் ☐

4.2 இஸ்லாமிய மதம் ☐

4.3 கிறிஸ்தவ மதம் ☐

4.4 பிறமதம் ☐

5 . வீடு உள்ள இடம்

5.1 நகரம் ☐

5.2 நகரியம் ☐

5.3 கிராமம் ☐

6 . குடும்ப மாத வருமானம் ரூபாயில்

6. 1 < 5000 ☐

6. 2 5001 - 10000 ☐

6. 3 10001 - 15000 ☐

6. 4 > 15001 ☐

APPENDIX –XIII

PROFORMA FOR CLINICAL VARIABLES

Purpose

This proforma is used to collect the information of children from the parents, such as type of injection, previous hospitalization and allergic reaction

Instruction

The researcher collects the information from the parents through interview and by referring hospital records.

1. **Height of the child in centimeters**

   1.1 < 80 cms ☐

   1.2 81-85 cms ☐

   1.3 85-90 cms ☐

   1.4 > 90 cms ☐

2. **Weight of the child in kilograms**

   2.1 < 11kgs ☐

   2.2 11.1-12 kgs ☐

   2.3 12.1-13 kgs ☐

   2.4 > 13 kgs ☐

3. **Type of injection**

   3.1 DPT vaccine or DTPa booster – 1 ☐

   3.2 Pentavac ☐

   3.3 MMR -1 ☐

   3.4 Other IM injection, specify ☐

4. Previous hospitalization

4.1 Yes ☐

4.2 No ☐

5. History of any allergic reaction

5.1 Yes ☐

5.2 No ☐

மருத்துவ மாறிகளின் மாதிரிப் படிவம்

நோக்கம்

இந்த மாதிரிப்படிவம் குழந்தைக்கு அளிக்கப்படும் ஊசி, முன்பு மருத்துவமனையில் அளிக்கப்பட்ட சிகிச்சை, ஒவ்வாமை ஆகியவற்றைப் பற்றி குழந்தையின் தாயிடமிருந்து சேகரிக்கபட்டுள்ளது.

அறிவுரை

ஆவணங்களை படிப்பதன் மூலமும், தாய்யிடம் நேர்காணல் மூலமும் ஆய்வாளர் தகவல்களைச் சேகரிப்பார்.

1. குழந்தையின் உயரம்

1.1 < 80 செ.மீ ☐

1.2 81 - 85 செ.மீ ☐

1.3 85 - 90 செ.மீ ☐

1.4 > 90 செ.மீ ☐

2. குழந்தையின் எடை

2.1 < 11 கி.கி. ☐

2.2 11.1 - 12 கி.கி. ☐

2.8 12. 1 - 13 கி.கி. ☐

2.4 > 13 கி.கி. ☐

3. ஊசியின் வகை

3.1 முத்தடுப்பூசி ☐

3.2 பென்டாவக் ☐

3.3 எம்.எம்.ஆர் ☐

3.4 வேறு வகை தசை ஊசி ☐

4. குழந்தை முன்பு மருத்துவமனையில் அனுமதிக்கப்பட்டிருந்ததா?

4. 1 ஆம் ☐

4. 2 இல்லை ☐

5. குழந்தைக்கு ஏதேனும் ஒவ்வாமை ஏற்பட்டதுண்டா?

5.1 ஆம் ☐

5. 2 இல்லை ☐

APPENDIX –XIV

PAIN ASSESSMENT SCALE

FACE LEG ACTIVITY CRY CONSOLABILITY (FLACC) PAIN SCALE

Purpose

This scale is used to measure the pain perception of children during intra muscular injection as scored by researcher.

Instruction

The researcher scores the pain by observing the child during intra muscular injection and place a (√) mark in appropriate column.

Criteria	Score
Face 0- No particular expression or smile 1- Occasional grimace or frown , disinterested 2- Constant quivering chin, clenched jaw	
Legs 0- Normal position or relaxed 1- Uneasy, restless, tense 2- Kicking or legs drawn up	
Activity 0- Lying quietly, normal position, moves easily 1- Squirming, shifting back and forth, tense 2- Arched, rigid or jerky	

Cry 0- No cry 1- Moons or whimpers 2- Crying steadily	
Consol ability 0- Relaxed 1- Reassured by occasional touching , hugging, distractible 2- Difficulty to console or comfort	

SCORE INTERPRERTATION

0 : No pain

1-3 : Mild pain

4-6 : Moderate pain

7-10 : Severe pain

BLUE PRINT OF RATING SCALE ON LEVEL OF SATISFACTION OF MOTHERS REGARDING ICE CUBE APPLICATION DURING INTRA MUSCULAR INJECTION

SI. NO	CONTENT	ITEMS	TOTAL ITEMS	PERCENTAGE
1.	Researcher's capacity	1,2,3	3	30%
2.	Effects of intervention felt by mother	4,5,6	3	30%
3.	Effects of intervention in the child	7,8,9,10	4	40%
TOTAL			**10**	**100%**

திருப்தி நிலை பற்றிய நிழற்ப்பட திட்ட வரைவு

வ. எண்	பொருளடக்கம்	வகைகள்	மொத்த வகைகள்	சதவீதம்
1.	ஆய்வாளருக்கானக் கேள்விகள்	1,2,3	3	30 %
2.	தாய்க்கு இருந்த பலன்	4,5,6	3	30 %
3.	குழந்தைக்கு இருந்த பலன்	7,8,9,10	4	40 %
		மொத்தம்	**10**	**100 %**

APPENDIX –XV

RATING SCALE ON LEVEL OF SATISFACTION OF MOTHER REGARDING ICE CUBE APPLICATION DURING INTRA MUSCULAR INJECTION

Purpose

The rating scale is used by the researcher after intra muscular injection to assess the level of satisfaction of mothers on ice cube application during intra muscular injection and its effectiveness.

Instruction

The rating scale consists of 10 items. Kindly read and give your responses freely and frankly and responses will be confidential. The response ranges from highly satisfied to highly dissatisfied with scores 3, 2, 1, 0 respectively.

Sl. no.	Questions	Highly satisfied	Satisfied	Dissatisfied	Highly dissatisfied
1.	The prior information about the ice cube application given by researcher				
2.	Approach of the researcher				
3.	Presence of researcher during and after procedure				
4.	Effect of ice cube application prior to intra muscular injection				

5.	Anxiety level of the mother a) Prior to procedure b) During procedure c) After procedure				
6.	Duration of ice cube application				
7.	Comfort of the child a) Prior to procedure b) During procedure c) After procedure				
8.	Child's response to pain perception during intra muscular injection				
9.	Feeling of security to mother and child				
10.	Time taken to calm the child a) < 5 minutes b) 5-10 minutes c) > 10 minutes				

SCORE INTERPRETATION

SCORE	PRECENTAGE	INTERPRETATION
<12	<40%	Low satisfaction
12- 20	40-69%	Moderate satisfaction
21-30	70-100%	High satisfaction

தசை ஊசியின் போது பனிகட்டி பயன்பாடு பற்றி தாய்மார்களின் மனநிறைவு மதிப்பீடு அளவுகோல்

நோக்கம்

இந்த அளவு கோலானது பனிகட்டி பயன்பாட்டிற்குப் பிறகு தாய்மார்களுக்கு ஏற்பட்ட திருப்தியின் அளவையும், அதன் பயன்பாட்டையும் மதிப்பீடு செய்ய ஆய்வாளர் பயன்படுத்தியது.

அறிவுரை

இந்த அளவு கோலில் பத்துவகைகள் உள்ளன. தயவு கூர்ந்து இவற்றைப் படித்து உங்கள் பதில்களைச் சுதந்தரமாகவும் வெளிப்படையாகவும் அளிக்கவும். பதில்கள் பாதுகாக்கப்படும் பதில்களின் எல்லை மிகவும் திருப்தியிலிருந்து திருப்தியில்லை வரை இருக்கும்.

வ. எண்	**கேள்விகள்**	**மிகவும் திருப்தி**	**திருப்தி**	**திருப்தி இல்லை**	**மிகவும் திருப்தி இல்லை**
1.	பனிகட்டி பயன்பாடு பற்றி ஆய்வாளர் முன்னர் கொடுத்த தகவல்				
2.	ஆய்வாளர் அணுகுமுறை				
3.	ஆய்வாளர் உடன் இருந்தது				
4.	தசை ஊசியின் முன் பனி கட்டி பயன்பாட்டின் விளைவு				

5.	தாய்க்கு இருந்த பதட்டம் அ) செயல் முறைக்கு முன் ஆ) செயல் முறையின் போது இ) செய்முறைக்கு பின்னர்				
6.	பனிகட்டி விண்ணப்பக்காலம்				
7.	குழந்தையின் சௌகரியம் அ) செயல்முறைக்கு முன் ஆ) செயல் முறையின் போது இ) செய்முறைக்குப் பின்னர்				
8.	தசை ஊசியின் பொழுது குழந்தையின் வலி உணர்வு அறியும் ஆற்றலின் வெளிப்பாடு				
9.	தாய் மற்றும் சேயின் பாதுகாப்பு உணர்வு				
10.	குழந்தையை அமைதிப்படுத்த எடுத்துக் கொண்ட நேரம் A) < 5 நிமிடங்கள் B) 5- 10 நிமிடங்கள் C) > 10 நிமிடங்கள்				

மதிப்பெண் விளக்கம்

மதிப்பெண்	சதவீதம்	பொருள் விளக்கம்
< 12	40 %	குறைவான திருப்தி
12 - 20	40 - 69 %	மிதமான திருப்தி
21 - 30	70 - 100 %	மிகவும் திருப்தி

APPENDIX - XVI

MANUAL ON ICE CUBE APPLICATION OVER LI-4 POINT

Definition

Ice Cube application is the ice applied to the acupressure point and meridian. It is characterized by pressing and rubbing on the meridian, acupoint, muscles and the skin areas by pushing and stroking the meridians, kneading and grasping muscles and rubbing the skin.

Indication

- Pain reduction during injection

Contraindication

Ice cube Application should not be given

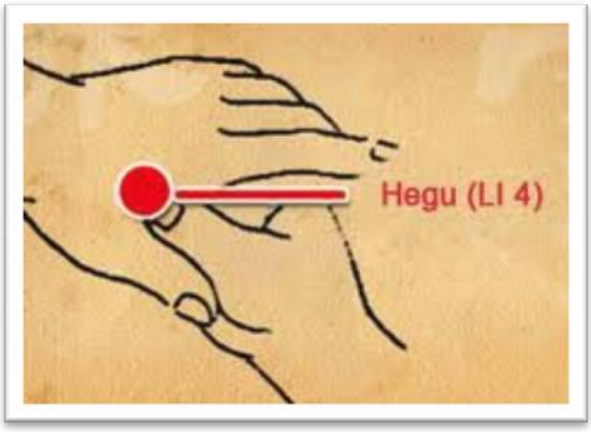
- In an area of infection
- Over red, broken or swollen skin
- Over major blood vessels

Mechanism of Action

Application of ice which stimulates the large diameter sensory fibers that synapse in the dorsal horn of the spinal cord which produces an inhibitory effect on the transmission of incoming pain signal, from smaller diameter sensory fibers stimulated by needle puncture, causes fewer pain signal to reach the brain and reducing perception of it.

Location

Large Intestine 4 (LI – 4) or Hegu is the point founded between the first and second metacarpal bones (bones of the thumb and first finger). It lies at the highest point formed when the thumb is brought to rest against the base of middle finger.



Steps for Ice Cube Application

- ✓ Tools needed are crushed ice, small terry wash cloth.
- ✓ Crushed ice is kept in the ice box.
- ✓ One third of the crushed ice is taken and placed in the center of the terry wash cloth.
- ✓ Four corners of the wash cloth are lifted to the center and twist it to make a small ice bag.
- ✓ The child is positioned comfortably on the mother's lap.
- ✓ The ice cube is applied for a period of 30 seconds prior to intra muscular injection.
- ✓ The ice cube application is repeated in both hands.

APPENDIX - XVII

DATA CODE SHEET

DV- Demographic variable

AGE - Age of the child

1.1 < 15 months
1.2 15-16 months
1.3 16-17 months
1.4 >17 months

GOC - Gender of the child

2.1 Male
2.2 Female

TOF - Type of family

3.1 Nuclear
3.2 Joint
3.3 Extended

Religion

4.1 Hindu
4.2 Muslim
4.3 Christian
4.4 Others, specify

AOR - Area of residence

5.1 Urban
5.2 sub urban
5.3 Rural

MI - Monthly Income in Rupees

6.1 < 5000
6.2 5001- 10000
6.3 10001- 15000
6.4 >15001

CV – Clinical variable

Height

1.1 < 80 cms
1.2 81-85 cms
1.3 85-90 cms
1.4 > 90 cms

Weight

2.1 < 11kgs
2.2 11.1-12 kgs
2.3 12.1-13 kgs
2.4 > 13 kgs

TOF - Type of Injection

3.1 DPT vaccine or DTPa booster – 1
3.2 Pentavac
3.3 MMR -1
3.4 Other IM injection, specify

PHH - Previous History of Hospitalization

4.1 Yes
4.2 No

HAR - History of Allergic Reaction

5.1 Yes
5.2 No

APPENDIX - XVIII

MASTER CODE SHEET

CONTROL GROUP													EXPERIMENTAL GROUP											
DV PROFORMA							CV PROFORMA					FLACC	DV POFORMA						CV PROFORMA					FLACC	SATIS.
S. NO	AGE	GOC	TOF	RELIGION	AOR	MI	H	WEIGHT	TOI	PHH	HAR	SCORE	AGE	GOC	TOF	RELIGION	AOR	MI	HEIGHT	WEIGHT	TOI	PHH	HAR	SCORE	SCORE
1	1.2	2.1	3.2	4.3	5.2	6.3	1.1	2.1	3.2	4.1	5.1	3	1.1	2.2	3.1	4.1	5.1	6.3	1.3	2.4	3.3	4.2	5.2	5	28
2	1.2	2.1	3.1	4.1	5.1	6.3	1.1	2.1	3.3	4.1	5.1	7	1.4	2.2	3.1	4.1	5.1	6.3	1.1	2.1	3.3	4.2	5.2	5	26
3	1.2	2.1	3.2	4.1	5.1	6.2	1.1	2.1	3.2	4.2	5.1	8	1.4	2.1	3.1	4.1	5.1	6.3	1.1	2.3	3.2	4.2	5.2	5	23
4	1.4	2.1	3.1	4.1	5.2	6.2	1.1	2.1	3.2	4.2	5.1	8	1.4	2.2	3.1	4.1	5.1	6.1	1.3	2.1	3.2	4.2	5.2	5	21
5	1.2	2.1	3.2	4.1	5.2	6.1	1.1	2.1	3.3	4.1	5.1	8	1.4	2.4	3.1	4.1	5.1	6.3	1.3	2.3	3.2	4.2	5.2	3	18
6	1.4	2.2	3.1	4.1	5.1	6.2	1.1	2.1	3.2	4.2	5.1	9	1.4	2.1	3.2	4.1	5.1	6.3	1.1	2.1	3.2	4.2	5.2	3	18
7	1.4	2.1	3.1	4.1	5.2	6.3	1.2	2.1	3.2	4.2	5.1	7	1.3	2.2	3.1	4.3	5.1	6.4	1.2	2.2	3.4	4.2	5.2	6	22
8	1.2	2.1	3.1	4.1	5.1	6.2	1.1	2.1	3.3	4.2	5.1	5	1.4	2.2	3.1	4.3	5.1	6.3	1.1	2.1	3.2	4.2	5.2	3	28
9	1.4	2.2	3.1	4.1	5.2	6.3	1.3	2.2	3.3	4.2	5.1	7	1.2	2.2	3.1	4.3	5.1	6.4	1.1	2.1	3.3	4.2	5.2	2	26
10	1.3	2.1	3.1	4.1	5.1	6.1	1.1	2.1	3.3	4.2	5.1	7	1.4	2.1	3.1	4.1	5.1	6.2	1.2	2.2	3.3	4.2	5.2	3	16
11	1.4	2.2	3.2	4.2	5.2	6.4	1.2	2.2	3.4	4.2	5.1	8	1.2	2.2	3.1	4.1	5.1	6.3	1.1	2.1	3.3	4.2	5.2	4	26
12	1.2	2.1	3.2	4.2	5.2	6.4	1.2	2.2	3.3	4.2	5.1	7	1.2	2.2	3.2	4.3	5.2	6.3	1.2	2.2	3.4	4.2	5.2	2	28
13	1.3	2.1	3.1	4.3	5.1	6.4	1.2	2.2	3.3	4.2	5.1	7	1.4	2.1	3.1	4.1	5.1	6.4	1.2	2.2	3.2	4.2	5.2	2	28
14	1.4	2.1	3.2	4.1	5.2	6.3	1.3	2.3	3.3	4.2	5.1	6	1.4	2.1	3.1	4.3	5.1	6.4	1.2	2.2	3.2	4.2	5.2	2	28
15	1.3	2.1	3.1	4.1	5.2	6.4	1.2	2.2	3.2	4.2	5.1	8	1.2	2.1	3.1	4.1	5.1	6.2	1.1	2.1	3.3	4.2	5.2	3	26
16	1.2	2.2	3.1	4.1	5.2	6.3	1.1	2.1	3.3	4.2	5.1	7	1.4	2.2	3.1	4.1	5.2	6.2	1.3	2.3	3.2	4.2	5.2	6	30
17	1.4	2.1	3.1	4.1	5.1	6.2	1.1	2.1	3.2	4.2	5.1	7	1.4	2.1	3.2	4.1	5.1	6.2	1.1	2.1	3.2	4.2	5.2	3	26
18	1.2	2.1	3.1	4.3	5.1	6.4	1.1	2.1	3.3	4.2	5.1	7	1.4	2.2	3.2	4.3	5.2	6.3	1.2	2.2	3.2	4.2	5.2	2	22
19	1.2	2.2	3.2	4.1	5.2	6.4	1.2	2.2	3.3	4.2	5.1	8	1.4	2.1	3.1	4.1	5.1	6.2	1.1	2.1	3.2	4.2	5.2	2	18
20	1.4	2.1	3.1	4.1	5.1	6.2	1.2	2.3	3.2	4.2	5.1	7	1.2	2.2	3.1	4.3	5.1	6.3	1.2	2.2	3.3	4.2	5.2	2	26
21	1.2	2.1	3.1	4.3	5.1	6.3	1.1	2.1	3.3	4.2	5.1	8	1.2	2.2	3.1	4.1	5.1	6.4	1.1	2.1	3.3	4.2	5.2	2	26
22	1.2	2.2	3.2	4.2	5.2	6.3	1.1	2.2	3.3	4.2	5.1	9	1.2	2.2	3.1	4.1	5.1	6.2	1.3	2.3	3.3	4.1	5.2	5	28
23	1.4	2.1	3.1	4.3	5.2	6.3	1.2	2.2	3.2	4.2	5.1	8	1.4	2.2	3.1	4.1	5.2	6.2	1.1	2.1	3.2	4.2	5.2	5	23
24	1.4	2.2	3.2	4.1	5.2	6.4	1.1	2.1	3.2	4.2	5.1	8	1.4	2.1	3.2	4.1	5.1	6.2	1.2	2.1	3.2	4.2	5.2	2	16
25	1.2	2.2	3.2	4.1	5.2	6.3	1.2	2.2	3.3	4.2	5.1	8	1.4	2.1	3.1	4.1	5.1	6.2	1.1	2.1	3.2	4.2	5.2	3	27
26	1.2	2.2	3.1	4.1	5.2	6.2	1.1	2.1	3.3	4.2	5.1	9	1.2	2.2	3.1	4.3	5.1	6.4	1.2	2.3	3.3	4.2	5.2	4	30
27	1.4	2.1	3.1	4.1	5.2	6.3	1.1	2.1	3.4	4.2	5.1	5	1.4	2.2	3.2	4.1	5.1	6.2	1.1	2.1	3.3	4.2	5.2	2	18
28	1.2	2.1	3.1	4.3	5.1	6.2	1.2	2.2	3.2	4.2	5.1	8	1.4	2.1	3.1	4.1	5.1	6.3	1.2	2.2	3.4	4.2	5.2	0	25
29	1.3	2.2	3.1	4.1	5.1	6.3	1.2	2.3	3.2	4.2	5.1	9	1.4	2.2	3.1	4.1	5.1	6.4	1.2	2.2	3.2	4.2	5.2	6	19
30	1.3	2.1	3.1	4.1	5.1	6.3	1.1	2.1	3.2	4.2	5.1	9	1.4	2.2	3.1	4.1	5.2	6.2	1.1	2.1	3.2	4.2	5.2	3	22

APPENDIX – XIX

PHOTOGRAPHS DURING THE STUDY


Punishable